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Food Safety and Inspection Service  
U.S. Department of Agriculture

# ABCs of BSE

Preventing Bovine Spongiform Encephalopathy  
from Entering the U.S. Meat Supply

Office of Public Affairs, Education and Outreach

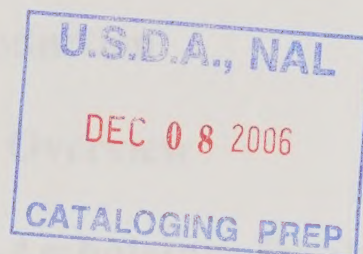
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U.S. Department of Agriculture



# ABCs of BSE

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# Introduction





### **FSIS' Authority**

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce.

Under the FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m) or if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601 (m) (3)).





# NEWS RELEASE

For more information, call (202) 720-4623 or visit the USDA website at [www.usda.gov](http://www.usda.gov).

Release No. 0449.03

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## VENEMAN ANNOUNCES ADDITIONAL PROTECTION MEASURES TO GUARD AGAINST BSE

WASHINGTON, Dec. 30, 2003—Agriculture Secretary Ann M. Veneman today announced additional safeguards to bolster the U.S. protection systems against Bovine Spongiform Encephalopathy, or BSE, and further protect public health.

"For more than a decade, the United States has had in place an aggressive surveillance, detection and response program for BSE," said Veneman. "While we are confident that the United States has safeguards and firewalls needed to protect public health, these additional actions will further strengthen our protection systems."

Veneman said the policies announced today have been under consideration for many months, especially since the finding of a case of BSE in Canada in May 2003. The policies will further strengthen protections against BSE by removing certain animals and specified risk material and tissues from the human food chain; requiring additional process controls for establishments using advanced meat recovery (AMR); holding meat from cattle that have been tested for BSE until the test has confirmed negative; and prohibiting the air-injection stunning of cattle.

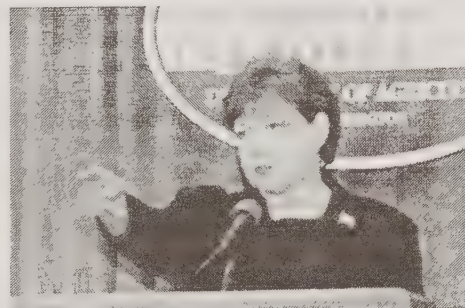
While many cattle in the United States can be identified through a variety of systems, the Secretary also announced that USDA will begin immediate implementation of a verifiable system of national animal identification. The development of such a system has been underway for more than a year and a half to achieve uniformity, consistency and efficiency across this national system.

"USDA has worked with partners at the federal and state levels and in industry for the past year and a half on the adoption of standards for a verifiable nationwide animal identification system to help enhance the speed and accuracy of our response to disease outbreaks across many different animal species," Veneman said. "I have asked USDA's Chief Information Officer to expedite the development of the technology architecture to implement this system."

"These are initial steps that USDA will take to enhance our protection system," Veneman said. "I am appointing an international panel of scientific experts to provide an objective review of our response actions and identify areas for potential additional enhancements."

Specifically, USDA will take the following actions:

**Downer Animals.** Effectively immediately, USDA will ban all downer cattle from the human food chain. USDA will continue its BSE surveillance program.



Agriculture Secretary Ann M. Veneman today announced additional safeguards to bolster the U.S. protection systems against Bovine Spongiform Encephalopathy, or BSE, and further protect public health.

Photo:DSC-3085.jpg

### Additional Information



spanish version



Additional BSE Information and Resources

**Product Holding.** USDA Food Safety and Inspection Service inspectors will no longer mark cattle tested for BSE as "inspected and passed" until confirmation is received that the animals have, in fact, tested negative for BSE. This new policy will be in the form of an interpretive rule that will be published in the Federal Register.

To prevent the entry into commerce of meat and meat food products that are adulterated, FSIS inspection program personnel perform ante- and post-mortem inspection of cattle that are slaughtered in the United States. As part of the ante-mortem inspection, FSIS personnel look for signs of disease, including signs of central nervous system impairment. Animals showing signs of systemic disease, including those exhibiting signs of neurologic impairment, are condemned. Meat from all condemned animals has never been permitted for use as human food.

**Specified Risk Material.** Effective immediately upon publication in the Federal Register, USDA will enhance its regulations by declaring as specified risk materials skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age and the small intestine of cattle of all ages, thus prohibiting their use in the human food supply. Tonsils from all cattle are already considered inedible and therefore do not enter the food supply. These enhancements are consistent with the actions taken by Canada after the discovery of BSE in May.

In an interim final rule, FSIS will require federally inspected establishments that slaughter cattle to develop, implement, and maintain procedures to remove, segregate, and dispose of these specified risk materials so that they cannot possibly enter the food chain. Plants must also make that information readily available for review by FSIS inspection personnel. FSIS has also developed procedures for verifying the approximate age of cattle that are slaughtered in official establishments. State inspected plants must have equivalent procedures in place.

**Advanced Meat Recovery.** AMR is an industrial technology that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material when operated properly. AMR product can be labeled as "meat." FSIS has previously had regulations in place that prohibit spinal cord from being included in products labeled as "meat." The regulation, effective upon publication in the Federal Register, expands that prohibition to include dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebrae column, in addition to spinal cord tissue. Like spinal cord, the dorsal root ganglia may also contain BSE infectivity if the animal is infected. In addition, because the vertebral column and skull in cattle 30 months and older will be considered inedible, it cannot be used for AMR.

In March 2003, FSIS began a routine regulatory sampling program for beef produced from AMR systems to ensure that spinal cord tissue is not present in this product. In a new interim final rule announced today, establishments have to ensure process control through verification testing to ensure that neither spinal cord nor dorsal root ganglia is present in the product.

**Air-Injection Stunning.** To ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process, FSIS is issuing a regulation to ban the practice of air-injection stunning.

**Mechanically Separated Meat.** USDA will prohibit use of mechanically separated meat in human food.

On Dec. 23, Veneman reported that a cow in Washington State has tested positive for BSE. A swift and comprehensive investigation is ongoing to trace the animal to a herd of origin, which is believed to be located in Alberta, Canada, as well as track additional animals that have entered the United States. (For the latest update on the investigation, visit [www.usda.gov](http://www.usda.gov).)

For more than a decade, the United States has had in place an aggressive surveillance, detection and response program for BSE. The United States has tested over 20,000 head of cattle for BSE in each of the past two years, 47 times the recommended international standard.

Since 1989, USDA has banned imports of live ruminants and most ruminant products from the United Kingdom and other countries having BSE.

In 1997, the FDA prohibited the use of most mammalian protein, the main pathway to spread the disease should it be in the United States, in the manufacture of animal feed intended for cattle and



other ruminants.

An independent analysis by Harvard in 2001 and again in 2003 shows that the risk of BSE spreading in the United States is low and any possible spread would have been reversed by the controls we have already put in place.

For more information please visit [www.usda.gov](http://www.usda.gov).

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In this rule, FSIS is requiring federally inspected establishments that slaughter cattle remove, segregate and dispose of these specified risk materials so that they cannot possibly enter the food chain. To facilitate the enforcement of this rule, FSIS has developed procedures for verifying the approximate age of cattle that are slaughtered in official establishments. State inspected plants must have equivalent procedures in place to prevent these specified risk materials from entering the food supply.

Comments on this interim final rule will be accepted for 90 days after the publication of the rule in the *Federal Register*. Comments should be directed to: FSIS Docket Clerk, Docket #03-025IF, Room 102, Cotton Annex, 300 12<sup>th</sup> and C Street, SW, Washington, DC 20250-3700.

**Advanced Meat Recovery.** AMR is a technology that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material. AMR product can be labeled as "meat." FSIS has previously established and enforced regulations that prohibit spinal cord from being included in products labeled as "meat."

This interim final rule expands that prohibition to include dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebral column, in addition to spinal cord tissue. In addition, because the vertebral column and skull in cattle 30 months and older will be considered inedible, they cannot be used for AMR.

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**Air-Injection Stunning.** To ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process, FSIS is issuing an interim final rule to ban the practice of air-injection stunning.

Comments on this interim final rule will be accepted for 90 days after the publication of the rule in the *Federal Register*. Comments should be directed to: FSIS Docket Clerk, Docket #01-033DF, Room 102, Cotton Annex, 300 12<sup>th</sup> and C Street, SW, Washington, DC 20250-3700.

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NOTE: Access news releases and other information at the FSIS web site at <http://www.fsis.usda.gov>.

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**For Further Information, Contact:**

FSIS Congressional and Public Affairs Staff

Phone: (202) 720-9113

Fax: (202) 690-0460

[News and Information Page](#) | [FSIS Home Page](#) | [USDA Home Page](#)







# BSE Overview



## Teaching Workshop

### Bovine Spongiform Encephalopathy (BSE)

Overview and Awareness Meetings



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## Definition of BSE

- Bovine Spongiform Encephalopathy:
  - A chronic degenerative disease affecting the central nervous system (CNS) of cattle
  - Commonly called "mad cow disease"

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## History of BSE

- First diagnosed in Great Britain in 1986
- Worldwide there have been more than 180,000 cases
  - 95% have been in the United Kingdom
  - In 22 countries, including the first positive in the U.S.

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### BSE Symptoms in Cattle

- Changes in temperament such as nervousness or aggression
- Abnormal posture
- Incoordination and difficulty in rising
- Decreased milk production
- Loss of body condition despite continued appetite

### BSE in Cattle

- No treatment
- No test to diagnose BSE in live animal
- Infective agent
  - Most accepted theory is that it is a prion, an abnormal form of a normal protein known as a cellular prion protein
- Data suggest that the cause may be animal feed containing contaminated meat and bone meal

### First BSE Positive in United States

- Presumptive positive on December 23, 2003
- Confirmed positive on December 25, 2003

### BSE Positive in U.S. – Timeline

- December 9, 2003
  - A non-ambulatory Holstein dairy cow arrives at Vern's Moses Lake Meats, in Moses Lake, Washington
  - Animal's condition attributed to complications from calving
  - Samples taken for the Animal and Plant Health Inspection Service (APHIS) BSE surveillance testing program

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### BSE – Timeline

- December 11
  - Samples arrive at USDA's National Veterinary Services Laboratories in Ames, Iowa
- December 22
  - Preliminary test results are positive

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### BSE – Timeline

- December 23
  - Further test results are positive
  - Agriculture Secretary Ann M. Veneman announces a "presumptive positive"
  - APHIS begins epidemiological investigation and places quarantine on herd where cow last resided in Mabton, Washington

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### BSE – Timeline

- December 24
  - FSIS initiates Class II recall of all meat (10,410 pounds) from group of 20 animals slaughtered at plant on December 9
  - APHIS determines disposition of three calves from the infected cow
- December 25
  - World reference laboratory in Weybridge, England confirms BSE positive

### BSE – Timeline

- December 27 – Traceback of infected cow indicates:
  - It was imported from Canada in 2001
  - Was likely 6 ½ years old, instead of the 4 ½ years the last owner's records indicated
  - Investigative efforts involve Canadian officials
- December 29
  - USDA identifies 8 more cows from the same herd in Canada that may have entered the U.S.

### BSE – Timeline

- December 30
  - Agriculture Secretary Veneman announces additional safeguards against BSE
- January 5
  - USDA announces decision to depopulate the bull calf operation in Sunnyside, Washington, that includes a calf born to the infected cow

## BSE – Timeline

### January 6

- DNA evidence helps to verify, with a high degree of certainty, that the BSE positive cow originated from a dairy farm in Alberta, Canada

### ■ January 12

- FSIS publishes 3 rules and a notice which take effect immediately

## Close Working Relationships

- Throughout this process, FSIS has worked closely with APHIS, state officials in affected states, and the Canadian Government.

## FSIS Regulatory Authority

- Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.)
  - FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce.
  - A meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m) (1) or if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601 (m) (3)).

### Published Following BSE Positive

- Published in *Federal Register* January 12, 2004:
  - Interim final rules with request for comments:
    - Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle
    - Advanced Meat Recovery (AMR) Systems
    - Prohibition of the use of air-injection stunning devices
  - Notice on BSE Surveillance Program

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### Awareness Meetings

- FSIS inspection program personnel held awareness meetings:
  - In all plants that slaughter cattle or process bone-in parts of cattle carcasses.
  - At the first weekly PBIS meeting after receipt of the awareness meetings notice.
  - To explain the new requirements.
  - To review 4 checklists with plant management.

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### Awareness Meetings

- FSIS inspection program personnel informed plant management:
  - Of the need to reassess the hazard analysis and determine what steps were necessary to ensure that the plant's products did not contain materials which might transmit BSE.
  - That if plants did not address procedures and controls, a Notice of Intended Enforcement (NOIE) was to be issued.

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### Documenting the Awareness Meetings

- Inspection program personnel documented the original awareness meetings in a memorandum of interview. It included:
  - Who was present.
  - Date and time the meeting was held.
  - What was discussed.
  - Any documents that were shared with plant management.

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### Awareness Meetings

- By the second weekly PBIS meeting:
  - FSIS inspection program personnel began verifying that the plant had incorporated appropriate procedures and controls into its:
    - Hazard Analysis and Critical Control Points (HACCP) Plan;
    - Sanitation Standard Operating Procedures (Sanitation SOPs);
    - Or prerequisite programs.

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### Awareness Meetings

- After the second weekly PBIS meeting,
  - Inspection program personnel verified that the requirements were being met utilizing the HACCP or the Sanitation SOPs procedure,
  - and documented noncompliance accordingly.

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### For More Information on BSE

- Log onto the FSIS website at

- <http://www.fsis.usda.gov/>

- Extensive USDA information

- Links to other BSE websites

- FSIS Technical Service Center (TSC)

- Phone 1-800-233-3935

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## **BSE Overview**

Bovine Spongiform Encephalopathy (BSE), or “Mad Cow Disease” as it is more commonly called, is a fatal and transmissible animal disease that affects the central nervous system of adult cattle. The first diagnosis of BSE was made in Great Britain in 1986. Cattle became infected after eating feed that contained a particular protein. The disease is most likely spread by feeding rendered parts of cattle infected with BSE to other cattle in the form of meat and bone meal.

In 1997, the U. S. Food and Drug Administration prohibited the use of feed containing the proteins that cause BSE. On December 23, 2003, Secretary of Agriculture, Ann M. Veneman announced that there was a “presumptive positive” case for BSE in the United States. The next day, the Food Safety and Inspection Service (FSIS) initiated a Class II recall of 10,410 pounds of meat from the group of 20 animals slaughtered at the plant that day. Testing continued in the United Kingdom, where it was confirmed positive on December 25, 2003.

On December 30, Secretary Veneman announced a number of safeguards to protect the public health and enhance protection against BSE, including the immediate banning of non-ambulatory disabled cattle from the human food supply.

On January 8, the U.S. Department of Agriculture announced three rules and a Notice. The rules went into effect on January 12. The ban on slaughter of non-ambulatory disabled cattle took effect upon the Secretary’s announcement.

### **Bovine Spongiform Encephalopathy Surveillance Program**

This notice announced that FSIS inspectors will no longer mark cattle tested for BSE as “inspected and passed” until confirmation is received by both FSIS and the plant that the cattle have, in fact, tested negative for BSE.

### **Prohibition of the Use of Specified Risk Materials for Human Food**

This interim final rule declares that skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age or older and the distal ileum and tonsils of all cattle are specified risk materials and cannot be used in human food. Tonsils from all cattle were already prohibited. In this rule, FSIS is requiring federally inspected establishments that slaughter cattle to remove, segregate and dispose of these specified risk materials so that they cannot possibly enter the food chain. To ensure effective removal of the distal ileum, the establishment is required to remove the entire small intestine from all cattle. To facilitate the enforcement of this rule, FSIS

has developed procedures for verifying the approximate age of cattle that are slaughtered in official establishments. State inspected plants must have equivalent procedures in place to prevent these specified risk materials from entering the food supply.

#### **Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems**

AMR is a technology that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material. AMR product can be labeled as “meat.” FSIS has previously established and enforced regulations that prohibit spinal cord from being included in products labeled as “meat.” This interim final rule prohibits dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebral column, in addition to spinal cord tissue. In addition, because the vertebral column and skull in cattle 30 months and older will be considered inedible, they cannot be used for AMR.

#### **Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter**

To ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process, this interim final rule bans the practice of air-injection stunning.

# Awareness Meeting



UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

# FSIS NOTICE

4-04

1/09/04

## AWARENESS MEETING REGARDING NEW REGULATIONS THAT PROHIBIT NON-AMBULATORY DISABLED CATTLE AND THE USE OF CERTAIN MATERIALS FROM CATTLE FOR HUMAN FOOD

FSIS will issue three regulations and a notice in the Federal Register on January 12, 2004, in response to the diagnosis by USDA of a positive case of BSE in an adult Holstein cow in the State of Washington. These regulations and the notice will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease.

The regulations prohibit the slaughter of non-ambulatory disabled cattle and identify a list of materials, including Specified Risk Materials (SRMs), that may present a risk for transmitting Bovine Spongiform Encephalopathy (BSE) and are now inedible:

☐ For all cattle:

- The tonsils are an SRM
- The small intestine -- the distal ileum is the SRM

☐ For cattle 30 months of age and older:

- The head – skull, eyes, brain, and trigeminal ganglia are the SRMs
- The vertebral column – spinal cord and dorsal root ganglia (DRG) are the

SRMs

Upon receipt of this FSIS notice, at establishments that slaughter cattle or establishments that process bone-in parts of cattle carcasses, inspection program personnel are to inform plant management through an awareness meeting about the new regulations and policies, inform them that the regulations are available on the FSIS website at <http://www.fsis.usda.gov/oa/news/2004/bseregs.htm>, provide them a copy of applicable checklists (see attachments), and inform them that as of Monday **January 12, 2004**, regulatory requirements will be in effect that prohibit the slaughter of non-ambulatory disabled cattle and that require establishments to ensure the removal,

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segregation, and disposition of SRMs. Inspection program personnel are to inform plant management that if an establishment slaughters non-ambulatory disabled cattle or fails to ensure the removal, segregation, and disposition of SRMs, inspection program personnel will take a regulatory control action as set out in 9 CFR 500.2(a)(3), *conditions preclude FSIS from determining that product is not adulterated*.

At the first weekly scheduled PBIS meeting after receipt of this FSIS notice, inspection program personnel are to review the applicable checklist with the plant management to ensure that the establishment understands what is required under the new regulations. Because the new regulations and policies are for the most part food safety related for beef products, inspection program personnel also are to inform the establishment that it is to reassess its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of materials that present the risk of transmitting BSE infectivity. Also at this meeting, inspection program personnel are to inform plant management that by the time of the second weekly PBIS-scheduled meeting, inspection program personnel will begin to verify that the establishment has incorporated the appropriate procedures and controls into Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operating Procedures (Sanitation SOPs), or prerequisite programs as required by the new regulations. Inspection program personnel also are to inform plant management that if it does not address procedures and controls in its HACCP plans, Sanitation SOPs, or prerequisite programs, a Notice of Intended Enforcement Action will be issued.

In a **memorandum of interview**, inspection program personnel are to document who was present at the initial awareness meeting, the date and time of the meeting, what was discussed, and any documents that were shared with management. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the plant management.

In the interim period prior to the second weekly scheduled PBIS meeting, while the establishment is reassessing the HACCP plan(s), if inspection program personnel identify noncompliance it will be documented as 06D01 using the "product based" trend indicator.

At the second weekly scheduled PBIS meeting, inspection program personnel are to verify that the establishment has addressed, in writing, the necessary procedures and controls within the HACCP plan, Sanitation SOPs, or prerequisite program.

After the second weekly scheduled PBIS meeting, inspection program personnel will verify that the requirements are being met utilizing the HACCP or the Sanitation SOPs procedure and document noncompliance accordingly.

*/s/ Philip S. Derfler*

Assistant Administrator  
Office Policy and Program Development

## **Checklist for New Regulations Regarding Non-Ambulatory Disabled Cattle and Stunning**

### **Is the establishment aware:**

- ☐ that non-ambulatory disabled livestock, including cattle, are now defined in 9 CFR 309.2(b) as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions?
- ☐ that the new regulations state that non-ambulatory disabled cattle are to be condemned and disposed of in accordance with 9 CFR 309.13?
- ☐ that cattle, regardless of whether they are non-ambulatory disabled, can no longer be slaughtered under the emergency slaughter provisions of the regulations, in modified 9 CFR 311.27?
- ☐ that captive bolt stunners that deliberately inject compressed air (air injection stunning) into the cranium at the end of the penetration cycle shall not be used to stun cattle (see 9 CFR 3313.15(b)(2)(ii))?
- ☐ that the heads from cattle 30 months of age or older are to be condemned unless the establishment can ensure that the stunning does not result in brain leakage onto the head?
- ☐ that cattle selected by APHIS for BSE Surveillance testing that are not non-ambulatory disabled are slaughtered but will be held and are not "inspected and passed" until the results of the test are received and are negative?

### **Has the establishment addressed:**

- o What is being done to ensure that these cattle do not enter the establishment?
- o What is being done to ensure that these cattle are humanely handled and killed in a timely fashion, and removed from the premises to prevent insanitary conditions?

## **Checklist for New Regulations Regarding Specified Risk Materials (SRMs) in Slaughter Operations**

### **Is the establishment aware:**

☐ that the regulations at 9 CFR 310.22(a) designate the following materials as SRMs and prohibit their use for human food:

(1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and

(2) the tonsils and the distal ileum (distal ileum is a SRM, but to ensure effective removal of the distal ileum, the establishment is required to remove the entire small intestine from all cattle)?

☐ that if it does not segregate cattle 30 months of age and older from younger cattle it is to handle all cattle as if they were 30 months of age and older?

☐ that it is recommended if old and young cattle are slaughtered and intended to be segregated, that the young cattle are slaughtered before old cattle or that the equipment used on the cattle 30 months of age and older is sanitized and there is no cross-contamination of carcasses less than 30 months of age.

### **Has the establishment addressed:**

o How it will ensure appropriate segregation and disposal of the small intestine and tonsils of all cattle?

o How it will determine age of cattle, such as by records or dentition?

o How it will segregate cattle 30 months of age and older from cattle younger than 30 months.

o How it is removing, segregating, and disposing of SRMs to ensure that there is no cross-contamination with edible product? (**NOTE:** For example, the vertebral columns from cattle 30 months of age and older do not have to be removed during the slaughter operation. However, if they are not removed in the slaughter operation, procedures must be put in place to ensure that the vertebral columns are adequately identified as being from cattle 30 months of age and older and the documentation transfers with the vertebral columns until they are appropriately disposed of as inedible.)



## **Checklist for New Regulations Affecting Boning Operations for Bone-in Parts, Including Bones, of Cattle Carcasses**

### **Is the establishment aware:**

☐ that the new regulations (9 CFR 310.22) prohibit the use of the skulls and vertebral columns from cattle 30 months of age and older (except for the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum)? (**NOTE:** Parts of carcasses 30 months of age and older can enter the boning operation, post-slaughter and post-chill, for the removal of the SRMs).

☐ that if it does not have documentation about the age of the cattle from which vertebral columns are derived, it is to handle all skulls and vertebral columns as if they were from cattle 30 months of age and older?

☐ that the traditional T-bone or porterhouse steaks and bone-in rib roasts can no longer come from cattle 30 months of age and older (i.e., a portion of the vertebral column bone defining these cuts of meat must now be removed, resulting in a semi-boneless cut of meat)?

### **Has the establishment addressed:**

☐ How it receives documentation from the slaughter operation regarding the age of cattle from which the skulls and vertebral columns are derived?

☐ How it will segregate the skull and prohibited sections of the vertebral column from cattle 30 months of age and older (i.e., the bones that contain central nervous system-type tissues) from all other bones?

## **Checklist for New Regulations Affecting Beef Used in Advanced Meat Recovery (AMR) Systems**

### **Is the establishment aware:**

☐ that the new regulations (9 CFR 318.24) prohibit the use of the skulls or vertebral columns (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum bones) of cattle 30 months of age or older from use in an AMR system?

☐ that the new regulations (9 CFR 318.24) prohibit product derived from AMR systems from the bones of cattle of any age from containing any central nervous system-type tissues (i.e., brain and trigeminal ganglia from the skull, or spinal cord and DRG from the vertebral column)?

☐ that the new regulations (9 CFR 319.5) prohibit the use of Mechanically Separated (Beef) and that these labels will be rescinded?

☐ that there are additional new non-food safety related regulatory requirements (9 CFR 318.24) related to the production of AMR for bone solids (calcium) and bone marrow (iron)?

### **Has the establishment addressed:**

☐ how it segregates skulls and vertebral columns from cattle 30 months of age and older from skulls and vertebral columns from cattle younger than 30 months?

☐ how it will prevent product derived from AMR systems from containing brain, trigeminal ganglia, spinal cord, or DRG?



UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

FSIS NOTICE	7-04	1/14/04
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QUESTIONS AND ANSWERS FOR FSIS NOTICE 4-04  
REGARDING FSIS's BSE REGULATIONS

**I. PURPOSE**

FSIS is issuing this notice as a supplement to FSIS 4-04, Awareness Meeting Regarding New Regulations That Prohibit Non-Ambulatory Disabled Cattle and The Use Of Certain Materials From Cattle For Human Food. This notice provides questions and answers regarding the instructions in FSIS Notice 4-04. No information in FSIS Notice 4-04 has change and these questions and answers serve as an attachment to that notice. However, under its administrative procedures, FSIS does not amend attachments to FSIS Notices; therefore, it is necessary to issue the questions and answers in this separate notice.

**II. QUESTIONS AND ANSWERS**

**Question:** FSIS Notice 4-04 explains that that the heads from cattle 30 months of age and older are to be condemned unless the establishment can ensure that the stunning does not result in brain leakage onto the head. Can the plant have written procedures in place to control or prevent contamination of edible portions with SRMs prior to washing?

**Answer:** Yes

**Question:** Does this written procedure apply to carcasses as well?

**Answer:** Yes

**Question:** If there is a control program in place and incidental contamination with SRMs (e.g. brain or spinal cord) occurs, can the product be reconditioned?

**Answer:** Yes, incidental contamination with readily identifiable SRMs can be removed by knife trimming.

**Question:** What is readily identifiable SRM contamination?

**Answer:** Contamination with material grossly identifiable as brain material, spinal cord, or fluid from punctured eyes.

**NOTE:** Cerebral fluid and spinal fluid are not SRMs.

**Question:** Can measures other than knife trimming be used to remove incidental SRM contamination?

**Answer:** There may be other acceptable methods. The establishment must have a supported and validated method of SRM removal that meets the requirements of 9 CFR Part 417.

**Question:** Who is responsible for the verification of these procedures?

**Answer:** The offline inspection personnel will verify the implementation of the procedures. If online inspection personnel observe visible (readily identifiable) SRMs, they should stop the line or have the head or carcass railed out for reconditioning and call for verification of process control by the offline inspection personnel.

**NOTE:** An establishment can choose to condemn heads that are contaminated with SRMs.

*/s/ Philip S. Derfler*

Assistant Administrator

Office of Policy and Program Development

<b>DISTRIBUTION:</b> Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices	<b>NOTICE EXPIRES:</b> 2/01/05	<b>OPI:</b> OPPD
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[Go Top](#)

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FSIS is in the process of developing a mechanism for electronic  
submittal of comments via e-mail – stay posted.

Send mail to [webmaster](mailto:webmaster) with questions or comments about this web site.  
Last modified: January 16, 2004





# Non-Ambulatory Disabled Cattle





## Teaching Workshop

### Bovine Spongiform Encephalopathy (BSE)

#### Non-ambulatory Disabled Cattle



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#### Non-ambulatory Disabled Cattle

- On January 12, 2004, FSIS issued an interim final rule that covered:
  - Requirements for the disposition of non-ambulatory disabled cattle.
  - As well as the prohibition of Specified Risk Materials (SRMs) in human food.

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#### Definition

- Non-ambulatory disabled cattle are:
  - [Cattle] "that cannot rise from a recumbent position or cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions."

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### BSE Risks

- Surveillance data from European countries with BSE indicate that the cattle with a greater incidence of BSE are:
  - Dead cattle
  - Cattle that cannot rise from a recumbent position
  - Cattle that show clinical signs of a Central Nervous System (CNS) disorder

### BSE Risks

- Testing
  - There is no sensitive and reliable test for BSE in live animals.
  - Post-mortem tests:
    - Can only indicate that cattle have the disease, at the earliest, two to three months before the onset of the clinical disease.
    - May show negative for an animal which does have BSE.

### BSE Surveillance in Europe

- Has also shown:
  - Clinical signs of BSE in non-ambulatory disabled cattle infected with BSE cannot always be differentiated from other conditions which may make the animal non-ambulatory disabled.

### Non-ambulatory Disabled Cattle

- Cannot be slaughtered
- Applies to:
  - Federally-inspected plants
  - State-inspected plants
  - Custom-exempt plants
  - Imports

### Non-ambulatory Disabled Cattle

- Include:
  - Animals which became non-ambulatory disabled on the way to the slaughter plant.
  - Animals which became non-ambulatory disabled on the plant premises, such as when they are being unloaded from the truck.

### Non-ambulatory Disabled Cattle

- In rare cases:
  - A normal, healthy animal sustains acute injury on the way to the knock box. The FSIS veterinarian can allow the animal to proceed to post-mortem.

### Cattle Prohibited from Slaughter

- Before January 12, 2004:
  - Dead (other than from slaughter)
  - Dying
  - Showing clinical signs of Central Nervous System (CNS) disorders
- Added on January 12, 2004:
  - Non-ambulatory disabled cattle

### Non-ambulatory Disabled Cattle

- All non-ambulatory disabled cattle presented for slaughter will be condemned.
  - They cannot be taken into the plant for slaughter or be conveyed to any part of the plant used for edible products.

### Non-ambulatory Disabled Cattle

- Plant must:
  - Humanely handle, euthanize, and remove them in a timely manner so that an insanitary condition does not arise.
- FSIS inspection personnel will verify that plant properly disposes of them.

### Emergency Slaughter

- Cattle can no longer be slaughtered under the emergency slaughter provisions.
  - Includes ambulatory cattle, as well as non-ambulatory disabled.
  - Previously allowed under Code of Federal Regulations 311.27.

### General FSIS Inspection Procedures

- FSIS veterinarian:
  - Conducts ante-mortem inspection on all abnormal cattle presented for slaughter.
  - Condemns all non-ambulatory disabled cattle.
  - Condemns all cattle showing CNS symptoms, even if animal is ambulatory.
- Non-ambulatory disabled cattle cannot enter plant.

### Removal for Other than Slaughter

- Owner or plant can request that condemned cattle be set apart and held for treatment.
- If livestock are removed for reasons other than slaughter, owner or plant must obtain permission from the local, State, or Federal livestock sanitary official having jurisdiction.

### Residue Issues

- Residue testing will continue as before on all cattle presented for slaughter.
- FSIS is concerned about the use of anti-inflammatory agents to assist animals in remaining ambulatory.
  - FSIS will continue special projects for these compounds and incorporate them into the enforcement program as soon as possible.

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### FSIS Guidance

- FSIS is continuing to issue notices and to provide answers to questions about non-ambulatory disabled cattle and other requirements published on January 12, 2004.
- We are attempting to answer all questions, whether at Teaching Workshops such as this, through the FSIS website, or through our Technical Service Center.

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## Food Safety and Inspection Service (FSIS) Requirements for Non-Ambulatory Disabled Cattle

Previous Requirements Before January 12, 2004	Current Requirements Beginning January 12, 2004
<b>Situation:</b> <ul style="list-style-type: none"> <li>No BSE positives had been found in the U.S.</li> </ul>	<b>Situation:</b> <ul style="list-style-type: none"> <li>The first BSE positive for a cow in the U.S. was confirmed on December 25, 2003.</li> </ul>
<b>Entities Affected:</b> <ul style="list-style-type: none"> <li>Federally-inspected plants</li> <li>State-inspected plants</li> </ul>	<b>Entities Affected:</b> <ul style="list-style-type: none"> <li>Federally-inspected plants</li> <li>State-inspected plants</li> <li>Custom-exempt plants</li> </ul>
<b>Cattle Prohibited from Slaughter:</b> <ul style="list-style-type: none"> <li>Dead or dying</li> <li>Showing clinical signs of Central Nervous System (CNS) disorder</li> </ul> <p>Note: All seriously crippled cattle and cattle commonly termed “downers” presented for slaughter were identified as “U.S. Suspects.” (9 Code of Federal Regulations 309.2(b))</p>	<b>Cattle Prohibited from Slaughter:</b> <ul style="list-style-type: none"> <li>Dead or dying</li> <li>Showing clinical signs of Central Nervous System (CNS) disorder</li> <li>Non-ambulatory disabled cattle – [Cattle] “that cannot rise from a recumbent position or cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions.”</li> </ul> <p>—They are <u>not</u> allowed to enter the plant. (Interim final rule and request for comments was published January 12, 2004. A notice has also been published.)</p>
<b>“Emergency Slaughter”</b> Injured livestock could be slaughtered for humane reasons at hours when ante-mortem inspection was not available, provided carcass and parts were kept for inspection. (11 Code of Federal Regulations 311.27)	<b>“Emergency Slaughter”</b> No longer allowed, even for ambulatory cattle. (11 Code of Federal Regulations 311.27 amended. Notice 4-04)
<b>Humane Slaughter Act:</b> Provisions apply.	<b>Humane Slaughter Act:</b> Provisions apply.
<b>Permission for removal of cattle for reasons other than slaughter:</b> <ul style="list-style-type: none"> <li>If livestock were removed for other than slaughter, plant or owner must obtain permission from local, State, or Federal livestock sanitary official having jurisdiction. (9 Code of Federal</li> </ul>	<b>Permission for removal of cattle for reasons other than slaughter:</b> <p>If livestock are removed for other than slaughter, plant or owner must obtain permission from local, State, or Federal livestock sanitary official having jurisdiction. (9 Code of Federal Regulations</p>

Regulations 309.13(d))	309.13(d))
<p><b>General Inspection Procedures:</b>            Certain Non-ambulatory Disabled Cattle were allowed to be slaughtered.</p> <ul style="list-style-type: none"> <li>• An FSIS veterinarian had to inspect non-ambulatory cattle before slaughter (ante-mortem inspection) and had three options:               <ol style="list-style-type: none"> <li>1. Hold the animal for further observation.</li> <li>2. Pass the animal for immediate slaughter as a U.S. Suspect animal.</li> <li>3. Condemn the animal. Animals <u>could not be slaughtered</u> and enter the human food chain if they were:                   <ul style="list-style-type: none"> <li>• Dead or dying,</li> <li>• Showed signs of Central Nervous System (CNS) disorders.</li> </ul> </li> </ol> </li> </ul> <p>(9 Code of Federal Regulations 309.2(b))</p> <p>Cattle that showed symptoms of Central Nervous System (CNS) disorders were condemned and humanely killed. FSIS veterinarians were instructed to:</p> <ul style="list-style-type: none"> <li>• Document all animal identification and ensure that it remained with the carcass (in case the animal would need to be traced back to its producer).</li> <li>• Notify the Animal and Plant Health Inspection Service (APHIS). An APHIS veterinarian would collect a sample of the brain tissue and submit it to the National Veterinary Services Laboratory.</li> <li>• Document the time, date and person notified in APHIS.</li> <li>• Assist APHIS in arrangements at the plant to collect the sample, so that the animal's disorder could be identified.</li> <li>• If APHIS was not immediately available, save the head, with brain intact, and chill (not freeze), so that samples would be available for APHIS.</li> <li>• Ensure that regulations were followed in disposing of the condemned carcass.</li> <li>• Ensure that humane slaughter procedures were followed. (FSIS Directive 6900.1, Revision 1, 11-2-98)</li> </ul>	<p><b>General Inspection Procedures:</b></p> <ul style="list-style-type: none"> <li>• <u>Non-ambulatory disabled cattle are not allowed to enter any Federal, State, or custom-exempt facility.</u> Procedures for disposing of the animal must be in place. (Interim final rule and request for comments was published January 12, 2004).</li> </ul> <p>FSIS veterinarian:</p> <ul style="list-style-type: none"> <li>• Conducts ante-mortem inspection on all non-ambulatory disabled cattle presented for slaughter.</li> <li>• Marks them "U.S. condemned."</li> <li>• Condemns all cattle showing CNS symptoms, even if animal is ambulatory.</li> <li>• Cattle condemned upon ante-mortem <u>cannot</u> enter plant.</li> <li>• If non-ambulatory or condemned for CNS symptoms, and there is reason to believe they are 20 months or older, inform APHIS Area Veterinarian-in-Charge (AVIC) to allow APHIS opportunity to collect BSE surveillance samples.</li> <li>• If a sample is collected, ensure all animal identification is maintained. Also, maintain control of the animal until plant documents how it will be properly disposed of.</li> <li>• If AVIC notifies FSIS Veterinarian that it is not possible to go to the plant, maintain control of the animal until the plant documents proper disposal.</li> <li>• Ensure that humane slaughter procedures are followed. (FSIS Directive 6900.1, Revision 1, 11-2-98)</li> <li>• Verify disposal of carcass. Can inform plant management that lined landfills are acceptable for disposal.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004. A notice has also been published.)</p> <ul style="list-style-type: none"> <li>• At request of owner or operator, condemned cattle can be set apart and</li> </ul>

	<p>held for treatment, under supervision of FSIS employee or designee of District Manager.</p> <ul style="list-style-type: none"> <li>• If an animal is released for purposes other than slaughter, owner or operator must first obtain permission from local, State, or Federal livestock sanitary official having jurisdiction.</li> <li>• In rare cases, a normal, healthy animal sustains acute injury on the way to the knock box. FSIS veterinarian can allow the animal to proceed to postmortem.</li> </ul>
<p><b>Testing Requirements:</b></p> <ul style="list-style-type: none"> <li>• The Animal and Plant Health Inspection Service (APHIS) randomly tested for BSE in cattle that appeared healthy (surveillance).</li> <li>• Meat from the tested healthy animals could be shipped into commerce before the test results were confirmed.</li> </ul> <p>APHIS also tested for BSE in non-ambulatory disabled cattle identified by FSIS veterinarians.</p>	<p><b>Testing Requirements:</b></p> <ul style="list-style-type: none"> <li>• The Animal and Plant Health Inspection Service (APHIS) randomly tests for BSE in cattle that appear healthy (surveillance).</li> <li>• Meat from tested cattle that appear healthy will be held until the tests are confirmed negative.</li> <li>• APHIS will continue BSE surveillance and testing at an increased rate.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004. A notice has also been published.)</p>
<p><b>Carcass disposal:</b></p> <ul style="list-style-type: none"> <li>• Plants were responsible for the disposal of carcasses of condemned cattle.</li> </ul>	<p><b>Carcass disposal:</b></p> <ul style="list-style-type: none"> <li>• Non-ambulatory disabled cattle will not be allowed to enter a plant.</li> <li>• FSIS will verify that plants properly dispose of condemned livestock.</li> </ul>





## Requirements for the Disposition of Non-Ambulatory Disabled Cattle.

New Regulatory Language	What it means
<p><b>PART 309—ANTE-MORTEM INSPECTION</b></p> <p>AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.</p> <p>2. Paragraph (b) of section 309.2 is revised to read as follows:  § 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.  * * * * *</p> <p>(b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.  * * * * *</p> <p>3. Section 309.3 is revised by adding a new paragraph (e) to read as follows:  * * * * *</p> <p>(e) Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with § 309.13.</p>	<p>Non-ambulatory disabled cattle are not allowed to enter the slaughter establishment and must be humanely handled and killed by the establishment. FSIS will record such cattle as “condemned” and ensure that the carcass is appropriately treated so that it doesn’t get into the human food chain. The condemned cattle must be disposed of in a timely manner so that an insanitary condition does not arise.</p>





**Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle  
During Slaughter**

New Regulatory Language	What it means
<p>PART 310—POST-MORTEM INSPECTION</p> <p>1. The authority citation for part 310 continues to read as follows: AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.</p> <p>2. Section 310.13 is amended as follows: Paragraph (a)(2)(iv)(C) is revised by adding the phrase “of all livestock except cattle” after “into the skull” and before “in conjunction with”.</p>	<p>Air-injection stunning of cattle is no longer allowed.</p>

New Regulatory Language	What it means
<p>PART 313 -- HUMANE SLAUGHTER OF LIVESTOCK</p> <p>3. The authority citation for part 313 continues to read as follows: AUTHORITY: 7 U.S.C. 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.</p> <p>2. Section 313.15 is amended as follows: Paragraph (b)(2) is revised by adding the words “and prohibitions” after the words “Special requirements” and before the period, by inserting an (i) before the words “Choice of instrument”, and by adding a new paragraph (ii) to read as follows: (ii) “Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle.”</p>	<p>Air-injection stunning of cattle is no longer allowed.</p>



**Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery  
(AMR) Systems**

New Regulatory Language	What it means
<p><b>PART 301-TERMINOLOGY</b></p> <p>1. The authority citation for part 301 continues to read as follows:  Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.</p> <p>2. In § 301.2, the definition of “Meat” is revised to read as follows:  §301.2 Definitions.  * * * * *</p> <p><i>Meat.</i> (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.</p> <p>(a) Meat does not include the muscle found in the lips, snout, or ears.</p> <p>(b) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).</p>	<p>“Meat” derived from Advanced Meat Recovery (AMS) systems can be labeled as “meat” if it does not violate criteria for CNS-type tissue, bone solids, or bone marrow.</p>

New Regulatory Language	What it means
<p><b>PART 318-ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS</b></p> <p>3. The authority citation for part 318 continues to read as follows:  Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, and 2.53.</p> <p>4. Section 318.24 is revised to read as</p>	

<p>follows:</p> <p>Product prepared using advanced meat/bone separation machinery; process control.</p> <p>(a) <i>General.</i> Meat, as defined in § 301.2 of this subchapter, may be derived by mechanically separating skeletal muscle tissue from the bones of livestock, other than skulls or vertebral column bones of cattle 30 months of age and older as provided in § 310.22 of this sub-chapter, using advances in mechanical meat/bone separation machinery (i.e., AMR systems) that, in accordance with this section, recover meat (1) without significant incorporation of bone solids or bone marrow as measured by the presence of calcium and iron in excess of the requirements in this section, and (2) without the</p>	<p>You can no longer use the skull or certain portions of the vertebral column from cattle 30 months of age and older in AMR systems.</p>
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<sup>1</sup> The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100g measured and rounded to the nearest 100<sup>th</sup> or more for that sample, minus the product of three factors: 1) the iron to protein ratio (IPR) factor associated with corresponding hand-deboned product; 2) the obtained protein (P) result (%) for that sample; and 3) a constant factor of 1.10. In formula, this can be written as:  $\text{ExcFe} = \text{mFe} - \text{IPR} \times \text{Protein} \times 1.10$ , where ExcFe represents the excess iron, expressed in units of mg/100g; mFe represents the measured level of iron (Fe, mg/100g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and "Protein" is the measured level of protein rounded to the nearest 100<sup>th</sup> and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.



<p>presence of any brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).</p> <p>(b) <i>Process control.</i> As a prerequisite to labeling or using product as meat derived by the mechanical separation of skeletal muscle tissue from livestock bones, the operator of an establishment must develop, implement, and maintain procedures that ensure that the establishment's production process is in control.</p> <p>(1) The production process is not in control if the skulls entering the AMR system contain any brain or trigeminal ganglia tissue, if the vertebral column bones entering the AMR system contain any spinal cord, if the recovered product fails otherwise under any provision of paragraph (c)(1), if the product is not properly labeled under the provisions of paragraph (c)(2), or if the spent bone materials are not properly handled under the provisions of paragraph (c)(3) of</p>	<p>A written program is required. If you process bones from cattle, the program must be a part of the HACCP plan, Sanitation SOP, or prerequisite program.</p>
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(2) this section.  
The establishment must document its production process controls in writing. The program must be designed to ensure the on-going effectiveness of the process controls. If the establishment processes cattle, the program must be in its HACCP plan, its Sanitation SOP, or other prerequisite program. The program shall describe the on-going verification activities that will be performed, including the observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord; the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG as prescribed in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these

If you use the skull or bone from the vertebral column, you must document when and how often you will observe the bones to ensure that they do not have brain, trigeminal ganglia, or spinal cord.

If you use the skull or bone from the vertebral column, you must document when and how often you will test the recovered product for spinal cord and DRG.

	<p>activities will be performed.</p> <p>(3) The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process.</p> <p>(4) The establishment shall make available to inspection program personnel the documentation described in paragraphs (b)(2) and (b)(3) of this section and any other data generated using these procedures.</p> <p>(c) <i>Noncomplying product</i> (1) Notwithstanding any other provision of this section, product that is recovered using advanced meat/bone separation machinery is not meat under any one or more of the following circumstances:</p> <p>(i) <i>Bone solids.</i> The product's calcium content, measured by individual samples and rounded to the nearest 10<sup>th</sup>, is more than 130.0 mg per 100 g.</p> <p>(ii) <i>Bone marrow.</i> The product's added iron content, measured by duplicate analyses</p>	
		<p>You must test the recovered product for bone solid content (excess calcium), bone marrow content (excess iron), spinal cord, and DRG.</p>

	<p>on individual samples and rounded to the nearest 10<sup>th</sup>, is more than 3.5 mg per 100 g<sup>1</sup>.</p> <p>(iii) <i>Brain or trigeminal ganglia.</i> Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.</p> <p>(iv) <i>Spinal cord.</i> Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.</p> <p>(v) <i>DRG.</i> The product that exits the AMR system contains DRG.</p>	
(2)	<p>If product that may not be labeled or used as “meat” under this section meets the requirements of § 319.5 of this subchapter, it may bear the name “Mechanically Separated (Species)” except as follows:</p> <p>(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR</p>	<p>You cannot label recovered product from beef that contain brain, trigeminal ganglia, spinal cord, or DRG as “meat,” “meat food product,” or “Mechanically Separated (Beef),” and such product must be designated for edible use (e.g., rendering)</p>

<p>system shall not be used as an ingredient of a meat food product.</p> <p>(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.</p> <p>(iii) If product derived from any bones of cattle of any age does not comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name “Mechanically Separated (Beef).”</p> <p>(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.</p>	
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New Regulatory Language	What it means
<p>PART 320-RECORDS, REGISTRATION AND REPORTING</p> <p>5. The authority citation for part 320 continues to read as follows:</p> <p>Authority: 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, and 2.53.</p> <p>6. Section 320.1, paragraph (b)(10), is amended by removing “of calcium content in meat derived from” and adding, in its place, “documenting the development, implementation,</p>	



and maintenance of procedures for the control of the production process using.”	
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## Regulatory Changes

NOTE: The interim final rule which includes the preamble and these changes follows this section.

### Prohibition of the Use of Specified Risk Materials for Human Food And Requirements for the Disposition of Non-Ambulatory Disabled Cattle

#### List of Subjects

##### 9 CFR Part 309

Ante-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 310

Post-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 311

Post-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 318

Entry into official establishments, reinspection and preparation of products.

##### 9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

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For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

#### PART 309--ANTE-MORTEM INSPECTION

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1. The authority citation for part 309 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

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2. Paragraph (b) of Sec. 309.2 is revised to read as follows:

Sec. 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

\* \* \* \* \*

(b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in Sec. 311.1 of this subchapter unless they are required to be classed as condemned under Sec. 309.3. Non-ambulatory disabled



livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

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3. Section 309.3 is revised by adding a new paragraph (e) to read as follows:

Sec. 309.3 Dead, dying, disabled, or diseased and similar livestock.

\* \* \* \* \*

(e) Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with Sec. 309.13.

#### PART 310--POST-MORTEM INSPECTION

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4. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

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5. A new Sec. 310.22 is added to read as follows:

Sec. 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older;

(2) The tonsils of all cattle; and

(3) The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(b) Specified risk materials are inedible and shall not be used for human food.

(c) Specified risk materials shall be disposed of in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(d) Procedures for the removal, segregation, and disposition of specified risk materials.

(1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that





the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified

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risk materials in preventing the use of these materials for human food and shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) Recordkeeping requirements. (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section shall be retained for at least one year and shall be accessible to FSIS. All such records shall be maintained at the official establishment 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(e) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

#### PART 311--DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

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6. The authority citation for part 311 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

#### Sec. 311.27 [Amended]

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7. Section 311.27 is amended as follows:

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a. By inserting ``of all livestock except for cattle'' in the first sentence after ``the carcass and all parts'' and before ``shall be kept for inspection''.

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b. By adding the following new sentence at the end of the paragraph:  
``The parts and carcasses of cattle slaughtered in the absence of an inspector shall not be used for human food.''



[Federal Register: January 12, 2004 (Volume 69, Number 7)]

[Rules and Regulations]

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Part V

Department of Agriculture

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Food Safety and Inspection Service

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9 CFR Part 301, 309, et al.

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice

[[Page 1862]]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319



[Docket No. 03-025IF]

Prohibition of the Use of Specified Risk Materials for Human Food  
and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule and request for comments.

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SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as "specified risk materials" (SRMs). The Agency is declaring that SRMs are inedible and prohibiting their use for human food. In addition, FSIS is requiring that all non-ambulatory disabled cattle presented for slaughter be condemned. The Agency is requiring that federally-inspected establishments that slaughter cattle and federally-inspected establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program. FSIS is taking this action in response to the diagnosis on December 23, 2003, by the U.S. Department of Agriculture of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington. This action will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. Infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with BSE at any stage of the disease.

DATES: This interim final rule is effective January 12, 2004. Comments on this interim final rule must be received by April 12, 2004.

ADDRESSES: Submit written comments to: FSIS Docket Clerk, Docket 03-025IF, Room 102, Cotton Annex, 300 12th and C Street, SW., Washington, DC 20250-3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday. Reference materials that are not copyrighted will also be available on the FSIS Web site at [http://http://www.fsis.usda.gov](http://www.fsis.usda.gov).

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202)205-0495.

SUPPLEMENTARY INFORMATION:





## Background

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce. The regulations, along with FSIS inspection programs, are designed to ensure that meat and meat food products are safe, wholesome, unadulterated, and properly marked, labeled, and packaged. The FMIA prohibits anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or meat food product (21 U.S.C. 610).

Under the FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1)) or if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3)). The FMIA requires that FSIS inspect the carcasses, parts of carcasses, and meat food products of all cattle, sheep, swine, goats, horses, mules, or other equines that are capable for use as human food to ensure that such articles are not adulterated (21 U.S.C. 604, 606). If the carcasses, parts of carcasses, and meat food products are found, upon inspection, to be not adulterated, FSIS marks them as "Inspected and passed" (21 U.S.C. 604, 606, 607). The FMIA gives FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Act (21 U.S.C. 621).

As discussed in greater detail below, infectivity has been confirmed in the brain, trigeminal ganglia, tonsils, spinal cord, DRG, and distal ileum of the small intestine of cattle experimentally infected with BSE, and in the brain, spinal cord, and eyes of cattle infected with BSE under field conditions. Data on the age distribution of clinical cases of BSE in the field reported in the United Kingdom indicate that clinical BSE disease has rarely been reported in cattle younger than 30 months of age.

In cattle experimentally infected with BSE, infectivity has been confirmed in the distal ileum at various stages of the disease process and as early as 6 months after oral exposure to the BSE agent. The tonsils of experimentally infected cattle have demonstrated apparently weak infectivity as early as 10 months after oral exposure to the BSE agent. The other tissues in which BSE infectivity has been confirmed have demonstrated infectivity at the end stages of disease, which, in experimentally infected cattle, was 32 months after exposure to the BSE agent and later. The brain, trigeminal ganglia, tonsils, DRG, and distal ileum are materials of experimentally infected cattle in which infectivity has been confirmed before the onset of clinical disease.

Based on these findings, FSIS has concluded that the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle are unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). Therefore, FSIS is designating these materials as SRMs, declaring that they are inedible and, pursuant to its authority to promulgate regulations necessary to carry out the provisions of the FMIA, prohibiting their use for human food.

Because there are currently no restrictions on the incorporation of spinal cord and DRG into MS(Beef) meat food product, such product may



contain concentrated amounts of these high-risk tissues. Therefore FSIS has concluded that, like the SRMs described above, MS(Beef) is unfit for human food under section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)).

As discussed in detail below, surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle. Surveillance data also indicate that clinical signs of BSE cannot always be observed in non-ambulatory cattle. Furthermore, due to limitations in the testing methods for BSE that are available today, certain tissues of cattle

[[Page 1863]]

infected with BSE may contain BSE infectivity even though the diagnostic test does not indicate that the animal has the disease. For the reasons presented above, FSIS believes that non-ambulatory disabled cattle present a risk of introducing the BSE agent into the human food supply. Therefore, FSIS has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the FMIA and that all non-ambulatory disabled cattle that are presented for slaughter should be condemned.

By declaring SRMs and MS(Beef) inedible and prohibiting their use for human food, and by condemning all non-ambulatory disabled cattle, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.

Because BSE was recently confirmed in a cow in the United States, FSIS has determined that the SRMs identified in this document are unfit for human food. Thus, the status of most of these materials has changed from edible to inedible. Such a change is likely to affect the underlying hazard analysis that must be conducted as prescribed by 9 CFR 417.4(a)(3). Therefore, in response to this change, FSIS expects that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRMs.

#### BSE and Variant Creutzfeldt-Jakob Disease

BSE is a progressive degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs), which include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Cruetzfeldt-Jakob disease (CJD) in humans. The typical incubation period (the time from when an animal becomes infected until it first shows disease signs) for BSE is believed to be from two to eight years. BSE was first documented in the United Kingdom in 1986 and has since been identified in approximately 21 other countries in Europe. BSE has also been confirmed in some non-European countries, including Japan, Israel, and Canada.

On December 23, 2003, USDA announced a presumptive diagnosis of BSE in an adult Holstein cow from Washington State. Samples were taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratory, Ames, Iowa. On December 25, 2003, the International Reference Laboratory in Weybridge, England confirmed the diagnosis of BSE.





The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein, although other types of agents have also been implicated. The agent is highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria.

In 1996, a newly recognized form of the human disease CJD, referred to as vCJD, was reported in the United Kingdom. Scientific and epidemiological studies have linked vCJD to exposure to BSE, probably through human consumption of beef products contaminated with the agent that causes BSE (Ref. 1-5 available for viewing by the public in the FSIS Docket Room). To date, approximately 150 probable and confirmed cases of vCJD have been reported worldwide.

The Centers for Disease Control and Prevention (CDC) leads a surveillance system for vCJD in the United States, and as of December, 2003, the disease has never been detected in residents of the United States that have never lived in or traveled to the United Kingdom for extended periods of time. In 2002, a probable case of vCJD was reported in a Florida resident who lived in the United Kingdom during the BSE epidemic. Epidemiological data indicate that the patient was likely exposed to the BSE agent before moving to the United States. (Ref. 6 available for viewing by the public in the FSIS Docket Room).

The United States government has implemented a number of measures to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into the United States. Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and certain cattle products, including rendered protein products, from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. In 1997, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds given to cattle and other ruminants. In December 2000, APHIS prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concern that feed intended for cattle may have been cross-contaminated with the BSE agent. In addition, APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the United States and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the United States. This plan was activated when the BSE test for the cow in Washington State came back presumptive positive on December 23, 2003. Other Federal agencies also have contingency plans that work in concert with the USDA plan.

#### BSE Infectivity

Animal age. The distribution and amount of the BSE agent in cattle infected with BSE is not known with certainty. It is generally accepted that in animals with clinical BSE disease, the brain and spinal cord contain the greatest concentration of the BSE agent, and that the quantity of the agent increases as the animals progress through the incubation period to the development of clinical disease. Thus, the total infective load in cattle in the early stages of the incubation period is believed to be much lower than in cattle approaching the end of the incubation period or in those cattle with overt clinical BSE. As



stated above, the typical incubation period for BSE is believed to be between two to eight years.

Information on the age at which cattle develop clinical BSE under field conditions, i.e., commercially reared cattle not part of a specially designed experiment, can be useful in identifying those cattle that, if infected with the BSE agent, are most likely to contain the highest levels of infectivity. Age-of-onset was known and recorded for approximately 135,000 cattle with confirmed clinical BSE in the United Kingdom between 1988 and August 2003 (Ref. 7, available for viewing by the public in the FSIS Docket Room). These data demonstrate that the age at which cattle develop clinical disease varies. The data from the United Kingdom show a gradual increase in the number of clinical BSE cases with increasing age, and that the number of confirmed cases peaks at 5 years of age. The lower ranges of this age distribution include some cattle younger than 30 months of age.

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The age distribution data show that, of the cattle that developed clinical BSE in the field, only 0.01% were less than 30 months of age. Thus, cattle younger than 30 months of age are less likely to be in the later stages of BSE incubation than older BSE-infected cattle, and hence, are less likely to contain high levels of BSE infectivity. Research demonstrates that the incubation period for BSE appears to be linked to the infectious dose of the BSE agent received, i.e., the larger the infectious dose received the shorter the incubation period (Ref. 8, available for viewing by the public in the FSIS docket room). Thus, given these observations, scientists that have studied the disease believe that the occurrence of BSE in young cattle is most likely the result of exposure to a very large dose of the BSE agent at a very young age.

Detection of BSE in cattle younger than 30 months of age. In October 2003, Japan reported a BSE case in a 23-month old bull, the 8th BSE case confirmed in that country. Earlier cases confirmed in Japan were in cattle over 5 years of age. This recent case apparently did not have clinical signs of disease and was detected as part of Japan's regular surveillance for BSE in which all cattle slaughtered for human consumption are screened for the disease. In reporting on this BSE case, Japanese officials stated that tests suggested that the form of the BSE agent found in the affected animal was atypical, and that they planned to conduct further studies on this form of the disease. A similar form of the atypical agent detected in the Japanese animal has been reported in two BSE cases in Italy. However the Italian animals were 11 and 12 years old. Japan has reported importing feed from Italy.

In early November 2003, shortly after reporting the confirmation of BSE in a 23-month-old animal, Japan reported that BSE was confirmed in a 21-month-old animal. The 21-month-old animal is Japan's 9th reported case of BSE. Like the 23-month-old animal, this animal apparently did not have clinical signs of disease. However, the abnormal prion protein detected in this animal does not appear to be the same as the apparently atypical form detected in the 23-month-old animal. Japanese officials reported that they will be conducting testing to determine if the tissues of these relatively young cattle that were recently found positive for BSE contain BSE infectivity.

The immediate implications of the recent detection of BSE in two animals younger than 24 months of age in Japan, one of which has an apparently atypical form of the disease, are not readily apparent at





this time. Although rare, confirmed cases of BSE in animals younger than 30 months of age have also been reported in the United Kingdom and in some other European countries. As stated earlier in this document, a confirmed case of BSE in an animal less than 30 months of age generally implies that the animal was exposed to a large dose of the infective agent at a young age. From 1988 to 1996, during the height of the BSE epidemic in the United Kingdom when large amounts of infective agent were being circulated among cattle herds, 19 clinical cases of BSE were confirmed in cattle younger than 30 months of age (Ref. 9, available for viewing by the public in the FSIS docket room). The youngest confirmed case of BSE was in the United Kingdom in an animal with clinical disease at 20 months of age in 1992. However, as of September 30, 2003, no cases of BSE in cattle younger than 30 months of age have been detected in the United Kingdom since 1996, and only 3 cases have been found in European animals less than 30 months of age since 2001.

FSIS requests comment on the potential implications, if any, of the reported 21- and 23-month-old cases of BSE in Japan. The Agency is also requesting comments on whether, and if so how, it should modify the measures in this rulemaking to address the fact that, in rare instances, BSE has been confirmed in cattle younger than 30 months of age.

Infective tissues. Available data on the development and distribution of tissue infectivity in BSE-infected cattle are incomplete. Most of what is known comes from pathogenesis studies conducted in the United Kingdom (Ref. 10, 11, 12 available for viewing by the public in the FSIS Docket Room). In these studies, cattle were deliberately infected with BSE through oral exposure to the brains of cattle with confirmed BSE. The experimentally infected cattle were killed at regular intervals as the disease developed, and at each interval the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. At each interval, tissues of the BSE infected cattle were also injected into mice to identify those tissues of cattle capable of transmitting the disease.

The pathogenesis studies involved a small number of cattle (30 animals) that received a large, uniform dose of the BSE agent at a very young age (4 months). Thus, the findings may not reflect the development and distribution of infectivity of cattle exposed to the BSE under field conditions, where the level and age of exposure to the BSE agent are unpredictable. Furthermore, the pathogenesis studies did not determine the rate at which the BSE agent increases in the tissues that have demonstrated infectivity or the tissues that the agent must pass through to reach its ultimate destination in the animal after it is ingested. However, the results of these studies are useful in that they provide experimental evidence of the distribution of the infective agent in BSE-infected cattle at various stages of the disease.

The pathogenesis studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, change over time, with the highest levels of infectivity detected in the brain and spinal cord at the end stages of disease. In the studies, some cattle exhibited clinical signs of BSE as early as 35 months post oral exposure to the BSE agent. By 37 months post oral exposure, all of the 5 animals that were still alive demonstrated clinical evidence of BSE (animals had been serially sacrificed at set intervals). In cattle with clinical BSE, infectivity was demonstrated in the brain, spinal cord, DRG, trigeminal ganglia, and the distal ileum of the small intestine.





(DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. ``DRG'' as used in this document has the same meaning as the term ``dorsal spinal nerve root ganglia.'' Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.)

In one set of animals, infectivity was demonstrated in the bone marrow at 38 months post exposure, but these findings were not conclusive. At this time, bone marrow is not designated as SRM. However, in today's Federal Register, FSIS is announcing new requirements to limit the presence of bone marrow in meat produced from AMR systems, with iron as a marker. This action is not a food safety measure at this time but is related to misbranding.

In some cattle in the studies, BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months post oral exposure to the BSE agent. In addition, infectivity was demonstrated in these tissues three months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months post oral exposure to the BSE agent and again at 38 months and 40 months post oral exposure.

A second phase of the pathogenesis studies that uses a cattle bioassay is being conducted to ensure that low levels of infectivity that may not have

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been detected in the first phase using the mouse bioassay are not missed. The cattle bioassay, in which tissues from cattle deliberately infected with BSE are injected directly into the brains of BSE-free cattle, is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay. Preliminary results from the cattle bioassay demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months post oral exposure to the BSE agent contain infectivity. However, because only one of five animals injected with infected tonsil material developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low. The second phase of the study is still underway and is not expected to be completed for several more years. (Ref. 8 and 13, available for viewing by the public in the FSIS Docket Room).

In cattle infected with BSE under field conditions, BSE infectivity has been confirmed in the brain, spinal cord, and retina of the eye at the end stages of the disease (Ref. 8 available for viewing by the public in the FSIS Docket Room).

BSE infectivity has never been demonstrated in the muscle tissue of cattle experimentally or naturally infected with the disease at any stage of the disease.

Proportion of infectivity in certain tissues. In 2001, the European Commission's Scientific Steering Committee (SSC), a scientific advisory committee for the European Union, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1% of the total infectivity in the animal and the spinal cord contains 25.6% of the total infectivity (Ref. 14 available for viewing by the public in the FSIS Docket Room). Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90% of the total infectivity in the animal. According to the SSC, the remaining proportion of infectivity in a typical animal with clinical BSE is



found in the DRG (3.8%), the trigeminal ganglia (2.6%), the distal ileum (3.3%), the spleen (0.3%), and the eyes (0.04%).\1\ However, as mentioned above, in experimentally infected cattle BSE infectivity has been demonstrated in the distal ileum as early as 6 to 18 months post oral exposure to the BSE agent and in the tonsils as early as 10 months post exposure. Thus, in younger cattle infected with BSE, these materials apparently present the greatest risk of exposing humans to the BSE agent.

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\1\ For this study, low levels of infectivity were assumed for the spleen and eyes based on scrapie experiments. The spleen has not demonstrated infectivity in cattle.

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#### Current Regulatory Requirements for Potentially Infective Materials

Under FSIS' regulations, most of the materials that have demonstrated BSE infectivity in cattle with clinical disease, i.e., brain, eyes, trigeminal ganglia, spinal cord, DRG, and the distal ileum of the small intestine, may currently be used in some way for human food. The brains of all livestock species, including the brains of cattle, are permitted for human food, with the exception of brains from animals stunned by lead, sponge iron, or frangible bullets (9 CFR 310.18(b)). Unprocessed cattle brains are typically sold chilled, frozen, or canned, and are consumed as a variety meat. Cattle brains may also be used as a by-product ingredient in certain processed products. When used as a by-product ingredient, cattle brains must be listed in the ingredients statement on the labeling of the product and declared by species (9 CFR 317.2(f)(1)).

Cattle brains are also permitted to be used as a source material in edible rendering. Edible rendering involves the processing of materials inspected and passed for human food into products, such as edible oils, meals, beef extracts, beef protein, beef broths, beef stocks, and beef flavorings. Many of these products are regulated by FSIS and FDA.

Given the invariable presence of bone splinters, detached spinal cords from all livestock species, including cattle, are prohibited for use in the preparation of edible products (9 CFR 318.6(b)(4)). However, detached spinal cords may be used as a raw material in edible rendering (9 CFR 318.6(b)(4)). The labeling of extracts prepared from brains, spinal cords, or other organs or parts of the carcass other than fresh meat from all livestock species, including cattle, must include the true name of the parts from which the product was prepared, e.g., ``extract from beef brain'' (9 CFR 317.8(b)(15)).

Vertebral columns from cattle contain both spinal cord and DRG. FSIS' regulations do not require that the spinal cord or DRG of cattle be removed from the vertebral column at the time of slaughter. Thus, some bone-in beef products may contain spinal cord, DRG, or both.

Bones from the vertebral column of cattle are permitted to be used as source materials in the production of processed products manufactured from edible rendering. When the vertebral columns from cattle are used in the production of such products, spinal cord and DRG that remain attached to the vertebral column could potentially become dislodged and incorporated into the final product. Under the FSIS regulations, the labeling of the final product is not required to disclose the fact that the product may contain spinal cord or DRG.

Bones from the vertebral column of cattle are also permitted for





use as a source material in meat recovery systems that use pressure to separate beef muscle tissue from bones. When the vertebral columns are used as a source material in these systems, spinal cord and DRG may become dislodged from the vertebral bones and incorporated into the final product. The use of vertebral columns in systems that mechanically separate meat and meat products from bone, and the labeling requirements for such products, are discussed in greater detail below.

Casings made from the small intestine, including the distal ileum, of cattle are permitted to be used as containers for meat food products (9 CFR 318.6(b)(1)). Cattle intestines, including the distal ileum, are also permitted for use as ingredients in meat food products that do not have an FSIS prescribed standard of identity, provided that the products are properly labeled (9 CFR 318.6(b)(8)).

FSIS' regulations do not prohibit the use of cattle eyes for human food, although direct consumption of such materials is uncommon in the United States. The tonsils of all livestock species, including cattle, are prohibited for use as ingredients of meat food products (9 CFR 318.6(b)(6)). The trigeminal ganglia of cattle are not sold directly as consumer products. However, the heads of cattle (commonly referred to as ``market heads'') are permitted for use as human food and are sold to retail establishments where they are used to produce edible products. Some retail establishments sell market heads of cattle directly to consumers. Cattle market heads contain skull, eyes, trigeminal ganglia, and fragments of brains.

Meat that has been trimmed from the head and cheeks of cattle is permitted to be used in FSIS-regulated products, although some product standards place certain restrictions on the use of head and cheek meat (for examples see 9 CFR 319.81, 9 CFR 319.199, 9 CFR 319.300 9 CFR 319.301, and 9 CFR.303) Head or cheek meat may contain CNS materials if the meat is not removed before the skull is fragmented or split. Although rare, the skulls of cattle are sometimes

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intentionally split to remove materials contained within the cranial cavity, such as the pituitary gland. The skulls of cattle are sometimes unintentionally fragmented, and the brains of the animals exposed, when a mechanical device is used to remove horns from cattle. In some instances, in addition to the fragmentation that occurs during horn removal, the brain has also been penetrated by the captive bolt of a stun gun, which results in a hole with weeping material that may contain CNS tissue. In these cases, when the head and cheek meat are removed, the heads of the cattle may be manipulated in such a way as to potentially contaminate the meat. Contamination of head or cheek meat with trigeminal ganglia is unlikely because the trigeminal ganglia are embedded within the skull and are not likely to be removed when the meat is harvested.

#### Meat Produced Using Advanced Meat Recovery Systems and Mechanically Separated (Species) Meat Food Product

Advanced Meat Recovery. Advanced Meat Recovery (AMR) is a technology that enables processors to remove the attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product. When produced properly, product from AMR systems is comparable to meat





derived by hand deboning and can be labeled as ``meat'' (9 CFR 301.2). Under the FSIS regulations, spinal cord is not a component of meat, and therefore, product from AMR systems identified as ``meat'' that contains spinal cord is misbranded.

From January through August 2002, FSIS conducted a survey of AMR products derived from the vertebral column of cattle to establish a baseline for the prevalence of spinal cord and DRG tissue in beef AMR products (referred to as the 2002 Beef AMR Survey) (Ref. 15 and 16, available for viewing by the public in the FSIS docket room and on the Internet at <http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf> and <http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf>). In the 2002 Beef AMR

Survey, the Agency found that while some establishments were able to consistently produce beef AMR product that was free of spinal cord and DRG tissue, a majority of the establishments had difficulty keeping spinal cord and DRG out of their AMR products. Overall, FSIS found that that approximately 76% (25 of 34) of the establishments whose AMR product was tested had positive laboratory results for spinal cord, DRG, or both in their final beef AMR products. The survey also found that approximately 35% (89 of 256) of all final AMR product samples that were tested had positive laboratory results for spinal cord, DRG, or both.

In March 2003, after completion of the 2002 Beef AMR Survey, FSIS implemented a routine regulatory sampling program of beef products from AMR systems as an additional measure to prevent misbranding of beef AMR products. Prior to the implementation of this regulatory sampling program, FSIS inspection program personnel collected AMR product samples for analysis for the presence of spinal cord tissue only if they believed that the establishment was not completely removing spinal cord from the vertebral column before the vertebral bones entered the AMR system (FSIS Directive 7160.2, April 14, 1997). Under the revised regulatory sampling program, FSIS inspection program personnel take samples of beef AMR product on a routine basis to verify that spinal cord tissue is not present in such product (FSIS Directive 7160.03, Revision 1, August 25, 2003). If spinal cord tissue is detected in beef AMR product, FSIS inspection program personnel take regulatory control action against the AMR product and equipment to prevent misbranded product from entering commerce. If the establishment has distributed misbranded beef AMR product, FSIS requests a voluntary recall.

Removal of the spinal cord before the vertebral columns enter the AMR system does not always ensure that spinal cord or DRG will not be incorporated into the final product. The Harvard study found that, if a beef carcass is mis-split when the spinal cord is removed, a portion of the spinal cord may remain encapsulated in the spinal canal of the vertebral column, and, if it is not removed before the vertebral bones enter the AMR system, the spinal cord could contaminate the final AMR product. Even when the spinal cord is completely removed from the vertebral column, the DRG of cattle are firmly attached to the bones of the vertebral column and are not removed along with the spinal cord. Thus, removing the spinal cord from the vertebral column does not prevent the DRG from entering an AMR system and becoming incorporated into the final AMR product.

Although FSIS and the regulated industry have recently taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products (Ref. 15 and 16, available for viewing by the public in the FSIS docket room), FSIS continues to



detect spinal cord and DRG in its routine regulatory sampling of beef AMR products, although to a lesser extent than it did in the 2002 Beef AMR Survey. In its routine regulatory sampling conducted from March to December in 2003, FSIS detected spinal cord in 23 of 340 randomly scheduled samples, an estimated prevalence of 6.8 percent. In addition, the prevalence in follow-up samples was 13.6 percent, indicating that establishments with an initial positive continued to have some problems controlling for spinal cord in beef AMR systems. While FSIS was testing samples for spinal cord, FSIS also recorded the results for DRG. The prevalence for DRG was found in 10.9 percent of the samples in which DRG was recorded.

Under the current regulations, AMR product that contains DRG is not misbranded and can be identified as meat. However, given the nature of DRG, and the fact that BSE has been confirmed in a cow in the United States, FSIS has reconsidered its approach to this tissue and is issuing a separate interim final rule on AMR systems in this edition of the Federal Register that reflects recent developments that have occurred with regard to BSE. The interim final rule on AMR systems also establishes non-compliance criteria to discern ``meat'' from non-meat product.

Mechanically Separated (MS)(Beef). MS(Beef) meat food product is a finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the regulation that prescribes the standard of identity for MS(Species). Unlike AMR systems in which bone and bone products are not purposefully incorporated in the final meat product, MS(Species) systems are designed to purposefully incorporate significant amounts of bone and bone components in the resulting meat food product. The specifications for product identified as MS(Species) in 9 CFR 319.5 do not establish limits on the incorporation of spinal cord or DRG into this product. Although beef products produced using AMR systems that contain spinal cord cannot be identified as meat, if these products meet the specifications contained in 9 CFR 319.5, they are permitted to be labeled as MS(Beef).

Under the current regulations, MS(Species) product is permitted for use as an ingredient in other processed meat and poultry products in limited amounts (9 CFR 319.6). When MS(Beef) is used as an ingredient in meat or poultry products, it must be identified in the ingredients statement as

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MS(Beef). However, the fact that MS(Beef) may contain spinal cord or DRG is not required to be conveyed on the labeling of MS(Beef) product or processed products that contain MS(Beef).

The fact that MS(beef) has been permitted to include spinal cord and DRG makes this product an obvious source of potential human exposure to the BSE agent. Given that a case of BSE was recently confirmed in the United States, FSIS believes that it is necessary to remove this high-risk product from the human food supply. Therefore, in this interim final rule, the Agency is banning the use of MS(beef) for human food. Accordingly, no product may bear the label (MS(Beef)). However, certain products from bones that do not contain CNS tissue, e.g., long bones, that may contain excess bone solids or bone marrow may be produced but must be labeled with an appropriate common or usual name (refer to the interim final rule, ``Meat Produced by Advanced





Meat/Bone Separation Machinery and Meat Recovery Systems,' ' docket number 03-038IF published in this edition of the Federal Register).

#### The Harvard Risk Assessment

In April 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the current measures implemented by the United States government to prevent the spread of BSE in the United States and to reduce the potential exposure of Americans to the BSE agent. The risk assessment (referred to below as the Harvard study) reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States (Ref. 17, available for viewing by the public in the FSIS docket room and on the Internet at <http://www.fsis.usda.gov/OA/topics/bse.htm>).

The Harvard study concluded that if introduced, due to the preventive measures currently in place in the United States, BSE is extremely unlikely to become established in the United States. Should BSE enter the United States, the Harvard study concluded that only a small amount of potentially infective tissues would likely reach the human food supply and be available for human consumption. The Harvard study expressed the amount of infectivity in terms of cattle oral ID50s for the purpose of quantifying both animal and human exposure to the BSE agent. A cattle oral ID50 is the amount of infectious tissue that would be expected to cause 50% of exposed cattle to develop BSE.

Because the exact quantitative relationship between human exposure to the BSE agent and the likelihood of human disease is unknown, the Harvard study did not evaluate the quantitative likelihood that humans will develop vCJD if BSE were introduced into the United States.

The Harvard study also did not address potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, and beef stocks, extracts, and flavorings. Many of these products are derived through the edible rendering process. FSIS is working with FDA, the agency that regulates the use of these products, to address the impact of this issue.

The Harvard study identified three pathways or practices that could contribute most to either human exposure to the BSE agent or to the spread of BSE should it be introduced into the United States. The three pathways are:

- [sbull] Noncompliance with FDA regulations prohibiting the use of certain proteins in feed for cattle and other ruminants;

- [sbull] Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed;

- [sbull] Inclusion of high-risk tissue from cattle, such as brain and spinal cord, in edible products.

FDA and USDA's APHIS are taking action to address the first two pathways. FDA is enhancing its enforcement of the feed ban and is evaluating whether further rulemaking is needed (see Advance Notice of Proposed Rulemaking, ``Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed,' ' 67 FR 67572, November 6, 2002). APHIS is developing approaches to control the potential risk that dead stock and non-ambulatory animals could serve as potential pathways for the spread of BSE (see Advance Notice of Proposed Rulemaking, ``Risk Reduction Strategies for Potential BSE





Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species," 68 FR 2703, January 21, 2003). FSIS is prohibiting the use of certain materials from cattle for human food to address the third potential pathway identified in the Harvard study, the inclusion of high-risk tissues in edible product. In addition, in a separate rulemaking published in this edition of the Federal Register, FSIS is prohibiting the use of penetrative stunning devices that inject air into the cranial cavity of cattle to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process (see "Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter," Docket 01-033IF). Although FSIS is not aware of any cattle slaughter establishments in the United States that use air-injection stunning, research has shown that this practice poses a risk of exposing humans to materials that could contain the BSE agent. Given that a case of BSE was recently confirmed in the United States, FSIS believes that this prohibition is a necessary measure to help strengthen the U.S. Government's actions to prevent human exposure to the BSE agent.

The Harvard study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, on average, three additional new cases of BSE in cattle would be expected. In fact, Harvard predicted that there was a 75 to 95% chance that there would be no new cases at all. The extreme case (95th percentile of the distribution) predicted 11 new cases. However, in all cases, the system in 2001 was robust enough so that model predicts that the disease would be quickly cleared from the United States with virtually no chance that there would be any infected animals 20 years following the import of the 10 infected cattle.

The Harvard study concluded the greatest sources of potential human exposure to the BSE agent would be human consumption of cattle brain (26% of the total potential exposure on average), cattle spinal cord (5% of the total potential exposure on average), and beef products derived from AMR systems (57% of the total potential exposure on average). The Harvard study also determined that other potential human exposure routes to the BSE agent include consumption of bone-in beef (11% of the total potential exposure on average), and intestine (2% of the total potential exposure on average). However, as stated in the Harvard study report, these estimates are likely to overstate true human exposure because they represent the amount of infectivity presented for human consumption but do not take into account waste or actual consumption rate. For example, the reported quantity for potential exposure to infectivity in bone-in beef reflects the presence of spinal cord and DRG in a fraction of cuts like T-bone steaks, although the spinal cord and DRG may never be consumed in these cuts of meat.

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The Harvard study divided potential sources of human exposure to BSE infectivity into two categories: specific high-risk tissues and contamination of low risk tissues with high-risk tissues. Specific high-risk tissues identified by Harvard, in order of infectivity, include: brain, spinal cord, DRG, distal ileum, and the trigeminal ganglia and other tissues found in the head (e.g., eyes). Since brain and spinal cord of cattle infected with BSE contain most of the BSE infectivity in the animal, the Harvard study concluded that, if BSE



were present in the United States, human consumption of bovine brains and spinal cords would be an obvious source of exposure to the BSE agent.

The Harvard study identified the production of meat through the use of AMR systems as the most important means by which low risk tissue can become contaminated with high-risk tissues because AMR systems can leave spinal cord and DRG in the recovered meat. Assuming that there is no SRM ban in place, the Harvard study estimated that beef AMR product could account for approximately 57% of the potential human exposure to the BSE agent.

#### Specified Risk Materials (SRMs)

Materials designated as SRMs. In determining which materials of cattle should be removed from the human food supply, FSIS considered the data on the age distribution of confirmed BSE cases in the United Kingdom, the findings of the pathogenesis studies conducted in the United Kingdom, and the findings of the BSE risk analysis conducted by Harvard.

After considering the factors mentioned above, together with the fact that a case of BSE was recently confirmed in the United States, FSIS has decided to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declare them inedible, and prohibit their use for human food. The Agency believes that removing these materials from the human food supply is a prudent and appropriate measure for preventing human exposure to the BSE agent in the United States.

Except for the skull and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) of cattle 30 months of age and older, the materials listed as SRMs in this interim final rule are all materials that have demonstrated infectivity in cattle naturally or experimentally infected with BSE. Thus, in this rule, FSIS is designating all materials from cattle that have demonstrated BSE infectivity as SRMs, regardless of the level or proportion of infectivity contained in each tissue.

Although the skull or vertebral column of cattle infected with BSE have not demonstrated infectivity, the skull contains the eyes, trigeminal ganglia, and brain, and the vertebral column contains DRG and spinal cord. Thus, because they contain high-risk tissues, FSIS is including skulls and vertebral columns (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older in the list of SRMs that the Agency is declaring inedible and prohibiting for human food. Head meat, cheek meat, and tongue are not part of the skull. Therefore, under this interim final rule, these materials may continue to be used for human food, provided they are not contaminated with SRM. Unlike other parts of the vertebral column, the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum do not contain spinal cord or DRG. Therefore, FSIS is excluding these parts of the vertebral column from the materials designated as SRMs. Under this interim final rule, bone-in beef from cattle 30 months of age and older may be prepared from these sections of the vertebral column. These sections of the





vertebral column may also be used as a source material for products produced from edible rendering.

The Harvard study identified the production of meat through the use of AMR systems as the most important means by which low risk tissue can become contaminated with high-risk tissues, such as spinal cord and DRG. Furthermore, as discussed above, although FSIS and the regulated industry have taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products, FSIS continues to detect spinal cord and DRG in its routine regulatory sampling of this product. By designating the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older as SRM and prohibiting its use for human food, FSIS will ensure that spinal cord and DRG from cattle 30 months of age and older are not incorporated into beef AMR product.

The Harvard study determined that some potential exposure to BSE infectivity would result from the presence of spinal cord and DRG in certain bone-in cuts of beef, such as T-bone steaks. By designating vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older as SRM and prohibiting its use for human food FSIS will ensure that bone-in cuts of meat from cattle 30 months of age and older will not contain spinal cord or DRG.

The Harvard study did not address potential human exposure to the BSE agent through beef stocks, broths, or other products produced from the edible rendering process. However, it is possible that, when vertebral column bones are used as a source material for products produced from edible rendering, spinal cord and DRG could become dislodged from the vertebral bones and incorporated into the final product. By designating vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older as SRM and prohibiting its use for human food FSIS will ensure that spinal cord and DRG from cattle 30 months of age and older will not be incorporated into beef products produced from the edible rendering process.

Because of its proximity to the vertebral column, some hand-deboned meat may contain DRG depending on the technique used to recover the meat from the bone. Thus, hand-deboned meat from cattle could be a potential source of human exposure to DRG. FSIS is not aware of any data on the extent to which DRG are found in hand-deboned meat. FSIS is examining this issue in a study it is conducting to delineate the characteristics of hand-deboned meat. FSIS is not, at this time, prohibiting hand-deboned meat from the vertebral columns of cattle 30 months of age and older for use as human food. The Agency requests comments on this issue.

The SRMs prohibited for human food in this interim final rule are the same materials prohibited for use as human food by Canada, thus establishing a consistent standard in both countries. The Canadian SRMs include the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and DRG from cattle 30 months of age and older, and distal ileum from all cattle. Although the vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar

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vertebrae, and the wings of the sacrum) from cattle 30 months of age





and older is not identified as SRM in the Canadian regulations, to ensure complete removal of potentially risky DRG from the human food supply, the Canadian Food Inspection Agency (CFIA) requires that the vertebral column of cattle 30 months of age and older, excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum, be removed and disposed of as inedible product (Meat Hygiene Directive 2003-18 (Amended), July 24 2003). The CFIA also prohibits the use of vertebral columns from cattle 30 months of age and older as a raw material in the preparation of mechanically separated meat or finely textured meat (Meat Hygiene Directive 2003-18 (Amended), July 24, 2003). The Canadian provisions for the removal of SRMs from the carcasses of cattle slaughtered in official Canadian establishments can be accessed on the Internet at <http://www.inspection.gc.ca/english/anim/meavia/mmopmmhv/chap4/annexne.sht>

The Canadian SRMs include the distal ileum from all cattle. However, the CFIA presently requires that the small intestine of all cattle be removed and disposed of as inedible product (Meat Hygiene Directive 2003-18 (Amended), July 24, 2003). Therefore, FSIS is designating, consistent with the Canadian rule, the distal ileum of the small intestine as SRM. To ensure that the distal ileum is completely removed from the carcass, FSIS is requiring that establishments remove the entire small intestine and that it be disposed of as inedible. Processors may be able to effectively remove just the distal ileum, and, accordingly, the Agency requests comments on this issue.

Rationale. Given the way that infectivity occurs in BSE-infected cattle, and the fact that a case of BSE has been detected in the United States, FSIS has determined that certain materials from cattle present sufficient risk of exposing humans to the BSE agent that it is prudent and appropriate to find that such materials are unfit for human food within the meaning of section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). For the reasons presented above, FSIS has concluded that these materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle.

The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle, present a persistent risk of exposing humans to the BSE agent because, in pre-clinical BSE-infected cattle, infectivity in most of these tissues is not readily ascertainable. Thus, humans could unknowingly be exposed to the BSE agent through consumption of these materials.

By designating the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age and older, and the tonsils and distal ileum of all cattle as SRMs, declaring that they are inedible, and prohibiting their use for human food, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.



#### Procedures for the Removal, Segregation, and Disposition of SRMs

In this interim final rule, FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs (section 310.22(d)(1)). The Agency is not prescribing specific procedures that establishments must follow because FSIS believes that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule.

Establishments are responsible for ensuring that SRMs are completely removed from the carcass, segregated from edible products, and disposed in an appropriate manner. Establishments must address their control procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs. FSIS will ensure the adequacy and effectiveness of the establishment's procedures.

This interim final rule also requires (section 310.22(d)(4)) that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and that the establishments make these records available to FSIS personnel on request.

FSIS will develop compliance guidelines for use by very small and small establishments to assist them in the development of validated methods for meeting the requirements of this interim final rule. FSIS believes that the use of the Canadian guidance on SRM removal generally is acceptable. FSIS will assess whether additional guidance is necessary (see the FSIS docket room and the FSIS Web site for the link to the Canadian and other compliance guidance information).

#### Verification of the Age of Cattle

Most of the materials that FSIS is prohibiting for use as human food in this rulemaking are from cattle 30 months of age and older. Thus, FSIS is prescribing the method that inspection program personnel will use to determine the age of cattle slaughtered in official establishments, to verify that the establishments are effectively segregating SRMs from edible materials.

The Agency is aware of two methods that can be used to verify the age of cattle slaughtered in official establishments: (1) Documentation that identifies the age of the animal, such as a birth certificate, cattle passport, or some other form of identification, that is presented with the animal when it arrives for slaughter, and (2) examination of the dentition of the animal to determine whether at least one of the second set of permanent incisors has erupted (the permanent incisors of cattle erupt from 24 through 30 months of age). The Agency has decided to use a combination of both methods.

If the establishment has records that document the age of the cattle slaughtered in the facility, FSIS inspection program personnel will examine the records. If the inspection program personnel conclude that the records are accurate and reliable, they will accept the records as verification of the age of the cattle. However, if FSIS inspection program personnel examine the records and find significant reasons for questioning their validity, they will verify the age of the cattle through dental examination. If the establishment does not have records that document the age of the cattle presented for slaughter, or the inspection program personnel have any reason to question the age of





the animals, the Agency will verify age through dental examination.

In establishments that only process the carcasses and parts of carcasses of cattle, the Agency will verify age through establishment records that document the age of the cattle from

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which the carcasses were derived. If the establishment does not have records that document the age of the cattle from which the carcasses were derived, it must handle all carcasses and parts of carcasses as if they came from cattle 30 months of age and older.

Although there are various methods of cattle identification in the United States, there is no national cattle identification system. Thus, there is currently no uniform standard of documentation that FSIS can rely on to accurately verify the age of cattle slaughtered in official establishments. On December 30, 2003, the Secretary of Agriculture announced that the USDA will implement a system of national animal identification. The development of such a system has been underway for more than a year and a half to achieve uniformity, consistency, and efficiency across this national system.

FSIS has developed instructions for use by its inspection personnel in verifying the age of cattle that is available for viewing by the public in the FSIS docket room and posted on the FSIS Web site.

#### Non-Ambulatory Disabled Cattle

Current regulatory requirements. FSIS' regulations prohibit for use as human food all livestock, including cattle, with clinical signs of a CNS disorder (9 CFR 309.4) and livestock that are in a dying condition or that died otherwise than by slaughter (9 CFR 309.3). Under the current regulation, all seriously crippled livestock and livestock commonly termed "downers" presented for slaughter are automatically suspected of being affected with a disease or condition that may require condemnation of the animal, in whole or in part, and are identified as "U.S. Suspects" (9 CFR 309.2(b)). Such animals are examined at ante-mortem inspection by an FSIS veterinarian, and a record of the veterinarian's clinical findings accompanies the carcass to post-mortem inspection if the animal is not condemned on ante-mortem inspection.

Post-mortem inspections of the carcasses of "U.S. Suspect" livestock are performed by veterinarians rather than by food inspectors, and the results of this inspection are recorded. "U.S. Suspects," unless otherwise released pursuant to 9 CFR 309.2(p), must be set apart and slaughtered separately (9 CFR 309.2(n)). If, on post-mortem inspection, the meat and meat food products from such animals are found to be not adulterated, such products may be used for human food (9 CFR 311.1).

Non-ambulatory cattle and BSE. Surveillance data from European countries in which BSE has been detected, indicate that cattle with clinical signs of a CNS disorder, dead cattle, and cattle that can not rise from a recumbent position (in Europe these cattle are distinguished either as "fallen stock" if not for human consumption or "emergency slaughter" cattle if for human consumption) have a greater incidence of BSE than healthy slaughter cattle. For example, in 2002 the EU reported that for healthy cattle 55-60 months of age, there were 0.55 positive tests for BSE per 10,000 animals tested compared with 3.05 positive tests for BSE per 10,000 cattle tested for the high-





risk cattle (i.e., fallen stock, emergency slaughter and animals that show clinical signs of BSE on ante-mortem inspection) (Ref. 18, available for viewing by the public in the FSIS docket room). In addition, an analysis of a targeted screening program for BSE in Switzerland found that when high-risk cattle were targeted for BSE testing, the odds of finding a BSE case was 49 times higher in fallen stock and 58 times higher in emergency-slaughtered cattle than in cattle tested under passive surveillance, i.e., clinical BSE suspects reported to the veterinary authorities (Ref. 19, available for viewing by the public in the FSIS docket room). This study also found that the BSE cases detected through targeted screening of high risk animals were on average four months younger than the BSE cases detected through passive surveillance of clinical suspects.

Surveillance for BSE in Europe has also shown that the typical clinical signs associated with BSE cannot always be observed in non-ambulatory cattle infected with BSE because the signs of BSE often cannot be differentiated from the typical clinical signs of the many other diseases and conditions affecting non-ambulatory cattle. Furthermore, as discussed in greater detail below, there are limitations with the diagnostic tests for BSE that are available today. Under the current testing methods, which are conducted on sections of the brain or spinal cord, certain tissues of cattle infected with BSE, such as the distal ileum and tonsils, may contain BSE infectivity even though the diagnostic test does not show that the animal has the disease. Thus, permitting the carcasses of non-ambulatory cattle to be used for human food if the animal tests negative for BSE will not provide the same level of protection against human exposure to the BSE agent that prohibiting these cattle from entering the human food supply will.

Revised regulatory requirements. Because they present a risk of introducing the BSE agent into the human food supply, FSIS has determined that the carcasses of non-ambulatory disabled cattle are unfit for human food under section 1(m)(3) of the FMIA and that all non-ambulatory disabled cattle that are presented for slaughter should be condemned. Therefore, FSIS is amending its ante-mortem inspection regulations to require the condemnation of non-ambulatory disabled cattle presented for slaughter.

Specifically, FSIS is amending the regulations that prescribe requirements for "U.S. Suspect" livestock in 9 CFR 309.2 by replacing the reference to "animals commonly termed 'downers'" in Sec. 309.2(b) with the term "non-ambulatory disabled livestock." FSIS is making this modification because there is currently no regulatory definition of "downer" and the Agency believes that the term "non-ambulatory disabled" more accurately describes the cattle that it believes should be prohibited for human food. "Non-ambulatory disabled livestock" is defined as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions. Thus, this definition includes livestock that are non-ambulatory due to an acute injury in route to the slaughter facility, such as a broken leg, as well as livestock that are non-ambulatory due to an underlying pathological condition.

FSIS is excluding all non-ambulatory disabled cattle from the human food supply, regardless of the reason for their non-ambulatory status or the time at which they became non-ambulatory. Thus, if an animal becomes non-ambulatory in route to the establishment due to an acute



injury, it must be humanely removed from the truck, humanely euthanized, and the carcass properly disposed of. Likewise, cattle that become non-ambulatory on the establishment premises, such as an animal that breaks its leg as it is unloaded from the truck, are also required to be humanely moved, humanely euthanized, and the carcass properly disposed of.

FSIS is also amending the regulations that prescribe requirements for dead, dying, disabled, or diseased and similar livestock in 9 CFR 309.3 to require that non-ambulatory disabled cattle be condemned and disposed of in accordance with 9 CFR 309.13. Unless another provision in part 309 applies, under Sec. 309.13, condemned livestock must be killed by the establishment, if

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not already dead. Such animals cannot be taken into the establishment to be slaughtered or dressed, or conveyed into any department of the establishment that is used for edible products. The carcasses of condemned livestock must be disposed of in the manner provided for in part 314.

Under part 314, condemned carcasses must be disposed of by "tanking," i.e., inedible rendering (9 CFR 314.1). For those establishments that do not have facilities for tanking, condemned carcasses may be disposed of by incineration or denatured by crude carbolic acid, cresylic disinfectant, a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or any other proprietary material approved by the Administrator of FSIS (9 CFR 314.3). The Agency is aware that many establishments use activated charcoal to denature inedible materials. Therefore, FSIS recognizes activated charcoal as a proprietary substance approved by the Administrator.

The regulations in 9 CFR 311.27 permit injured livestock to be slaughtered for humane reasons at hours when an inspector is not available to perform ante-mortem inspection, provided that the carcasses and parts of such animals are kept for inspection. To ensure that non-ambulatory disabled cattle are not slaughtered under this provision and their carcasses and parts used for human food, FSIS is amending 9 CFR 311.27 to prohibit the carcasses and parts of carcasses from cattle slaughtered on an emergency basis without ante-mortem inspection from being used for human food. Without performing ante-mortem inspection on cattle slaughtered on an emergency basis, FSIS inspection program personnel cannot determine whether the carcasses or parts from such cattle came from a non-ambulatory disabled animal, and thus cannot find that the carcasses and parts from these emergency slaughter cattle are not adulterated.

#### Testing Cattle for BSE

There is no sensitive and reliable live animal test for BSE, and the available post-mortem diagnostic tests can only indicate that cattle have the disease two to three months before the onset of clinical disease or after the onset of clinical disease. Given the limitations of the diagnostic tests available today, which are conducted on sections of the brain or spinal cord, certain tissues of cattle infected with BSE, such as distal ileum and small intestine, may contain BSE infectivity even though the diagnostic test will not show that the animal has the disease. Thus, exempting materials from cattle





that test negative for BSE from the restrictions in this rulemaking will likely not provide the same level of protection as prohibiting those materials for use as human food.

Therefore, under this interim final rule, the use of specified risk materials from cattle is prohibited for human food regardless of whether the animal has been tested for BSE. FSIS requests comments on whether further consideration should be given to exempting cattle that have tested negative for BSE from the requirements contained in this interim final rule, and if so, what testing methods and protocols the Agency should accept as providing acceptable and reliable results.

#### Request for Comments

FSIS requests comments on the measures contained in this interim final rule, and specifically on whether the Agency has chosen measures that are most appropriate for preventing human exposure to the BSE agent in the United States.

#### Emergency Action

The fact that a cow in Washington State tested as positive for BSE on December 23, 2003, makes this rulemaking necessary on an emergency basis. As discussed above, BSE infectivity has been confirmed in the brain, eyes, trigeminal ganglia, tonsils, spinal cord, DRG and distal ileum. Furthermore, most of these tissues have demonstrated infectivity before experimentally infected animals developed clinical signs of disease. Thus, BSE infectivity in these tissues is not readily ascertainable. Therefore, FSIS has determined that it must take immediate action to ensure that materials that could present a significant risk to human health are excluded from the human food supply.

Under these circumstances, the FSIS Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest, and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the Federal Register. FSIS will consider comments received during the comment period for this interim rule (see DATES above). After the comment period closes, the Agency will publish another document in the Federal Register. The document will include a discussion of any comments received in response to this interim rule and any amendments made as a result of those comments.

In an effort to ensure that establishments comply with this interim final rule upon publication in the Federal Register, FSIS will provide guidance to inspection program personnel regarding the implementation strategy. At a minimum, FSIS inspection program personnel will be directed to meet with management of each affected establishment to discuss how and when the establishment expects to complete its reassessment of its HACCP plan and to ensure that SRMs and MS (Beef) do not adulterate product.

#### Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. It has been determined to be economically significant for purposes of Executive Order 12866 and therefore, has been reviewed by the Office of Management and Budget (OMB).

The emergency situation surrounding this rulemaking makes timely





compliance with Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) impracticable.

FSIS is currently assessing the potential economic effects of this action. When this work is complete, the Agency will publish a notice of availability in the Federal Register and will provide an opportunity for public comment.

#### Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5. must be exhausted before any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

#### Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection and recordkeeping requirements included in this interim final rule have been submitted for emergency approval to the Office of Management and Budget (OMB).

Title: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle.

[[Page 1872]]

Type of collection: New.

Abstract: In this interim final rule, FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop written procedures for the removal, segregation, and disposition of SRMs. FSIS is also requiring that these establishments maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and any corrective actions taken. These records are needed for FSIS to verify the effectiveness of an establishment's procedures.

Estimate of burden: FSIS estimates that it will take establishments approximately 8 hours to develop written procedures for the removal, disposition, and segregation of SRMs. FSIS estimates that an establishment will spend about five minutes a day developing an average of nine monitoring records, which includes documentation of any corrective actions taken, and an additional two minutes a day to file each record.

Respondents: Official establishments that slaughter cattle and official establishments that process the carcasses or parts of cattle.

Estimated Number of Respondents: 2,500.

Estimated Number of Responses per Respondent: 2,701.

Estimated Total Annual Burden on Respondents: 807,500 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety



and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250 Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected, ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 30 days of the publication date of this interim final rule.

#### Government Paperwork Elimination Act (GPEA)

FSIS is committed to achieving the goals of the GPEA, which requires that Government agencies, in general, provide the public with the option of submitting information or transacting business electronically to the maximum extent possible. Under this interim final rule, records that document the implementation and monitoring of an establishment's procedures for the removal, segregation, and disposition of SRMs may be maintained on computers, provided that the establishment implements appropriate controls to ensure the integrity of the electronic data. Allowing establishments to comply with the required recordkeeping requirements will reduce data collection time, and information processing and handling by the regulated industry and FSIS.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this final interim final rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this Federal Register publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS Web page located at <http://www.fsis.u> The update is used to provide information regarding

FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.



## References

The following sources are referred to in this document. All have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday. Materials that are not copyright protected may also be accessed on the FSIS Web site as related documents to this interim final rule.

1. Will, R.G., et al., A new variant of Creutzfeldt-Jakob disease in the UK. *Lancet* 347, 921-925 (1996).
2. Collinge, J., et al., Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD. *Nature* 383, 685-690 (1996).
3. Bruce, M.E., et al., Transmission to mice indicates that 'new variant' CJD is caused by the BSE agent. *Nature* 389, 498-501 (1997).
4. Scott, M.R., et al., Compelling transgenic evidence for transmission of bovine spongiform encephalopathy prions to humans. *Proc Natl Acad Sci USA* 96, 15137-12142 (1997).
5. Belay, E.D., et al., Relationship between transmissible spongiform encephalopathies in animals and humans. In: Task Force Report of the Council for Agricultural Science and Technology. Washington, DC: Council for Agricultural Science and Technology, October 2002, No. 136.
6. MMWR, Probable Variant Creutzfeldt-Jakob Disease in a U.S. Resident--Florida, 2002, 51(41):927-929 (October 18, 2002).
7. Department for Environment Food and Rural Affairs, United Kingdom, FSIS personal communication.
8. European Union Scientific Steering Committee (EU SSC), 2002. Update on the Opinion of TSE infectivity distribution in ruminant tissues (initially adopted by the scientific steering committee at its meeting of 10-11 January 2002 and amended at its meeting of 7-8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection Food and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.
9. Department for Environment Food and Rural Affairs, United Kingdom, DEFRA BSE Information, Youngest and oldest cases by year of onset-GB (Passive surveillance only), September 30, 2003.

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10. Wells, G.A.H., et al., Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. *Veterinary Record* 135, 40-41 (1994).
11. Wells, G.A.H., et al., Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. *Veterinary Record* 142, 103-106 (1998).
12. Wells, G.A.H. Limited detection of sternal bone marrow infection in the clinical phase of experimental bovine spongiform encephalopathy. *Veterinary Record* 144, 292-294 (1999).
13. United Kingdom Food Standards Agency press release, Thursday, October 17, 2002.
14. European Union Scientific Steering Committee (EU SSC), 2001. Opinion of 10 December 1999 of the Scientific Steering Committee on the





Human Exposure Risk (HER) via Food with Respect to BSE.

15. Analysis of 2002 FSIS Bovine AMR Products Survey Results, prepared by the United States Department of Agriculture, Food Safety and Inspection Service, February 2003. Available on the Internet at <http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf>.

16. The Follow-up to the Beef AMR Product Survey of 2002: Follow-up Results and Actions for the Elimination of CNS (Spinal Cord) Tissues from AMR Products Derived from Beef Vertebrae, prepared by the Food Safety and Inspection Service, February 2003. Available on the Internet at <http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf>.

17. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.

18. European Commission, 2003. ``Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE) in 2002,`` p. 49.

19. Doherr, M.G., et al., Targeted screening of high-risk cattle populations for BSE to augment mandatory reporting of clinical suspects. Preventive Veterinary Medicine 51:1-2, 3-16 (2001).

#### List of Subjects

##### 9 CFR Part 309

Ante-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 310

Post-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 311

Post-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 318

Entry into official establishments, reinspection and preparation of products.

##### 9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

0

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

#### PART 309--ANTE-MORTEM INSPECTION

0

1. The authority citation for part 309 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.



0

2. Paragraph (b) of Sec. 309.2 is revised to read as follows:

Sec. 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

\* \* \* \* \*

(b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in Sec. 311.1 of this subchapter unless they are required to be classed as condemned under Sec. 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

\* \* \* \* \*

0

3. Section 309.3 is revised by adding a new paragraph (e) to read as follows:

Sec. 309.3 Dead, dying, disabled, or diseased and similar livestock.

\* \* \* \* \*

(e) Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with Sec. 309.13.

#### PART 310--POST-MORTEM INSPECTION

0

4. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

0

5. A new Sec. 310.22 is added to read as follows:

Sec. 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older;

(2) The tonsils of all cattle; and

(3) The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(b) Specified risk materials are inedible and shall not be used for





human food.

(c) Specified risk materials shall be disposed of in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(d) Procedures for the removal, segregation, and disposition of specified risk materials.

(1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program.

(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified

[[Page 1874]]

risk materials in preventing the use of these materials for human food and shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) Recordkeeping requirements. (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section shall be retained for at least one year and shall be accessible to FSIS. All such records shall be maintained at the official establishment 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(e) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

PART 311--DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

0

6. The authority citation for part 311 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.



Sec. 311.27 [Amended]

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7. Section 311.27 is amended as follows:

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a. By inserting ``of all livestock except for cattle'' in the first sentence after ``the carcass and all parts'' and before ``shall be kept for inspection''.

0

b. By adding the following new sentence at the end of the paragraph: ``The parts and carcasses of cattle slaughtered in the absence of an inspector shall not be used for human food.''

PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

0

8. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

Sec. 318.6 [Amended]

0

9. Section 318.6 is amended as follows:

0

a. Paragraph (b)(1) is amended by removing the word ``cattle'' and adding the following new sentence at the end of the paragraph: ``Casings from cattle may be used as containers of products provided the casings are not derived from the small intestine.''

0

b. Paragraph (b)(4) is amended by adding the following new sentence at the end of the paragraph: ``Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering.''

0

c. Paragraph (b)(8) is amended by adding the following new sentence at the end of the paragraph: ``The small intestine of cattle shall not be used in any meat food products or for edible rendering.''

PART 319--DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

0

10. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

0

11. Section 319.5 is amended as follows:

0

a. A new paragraph (b) is added to read as follows:



Sec. 319.5 Mechanically Separated Species.

\* \* \* \* \*

(b) Mechanically Separated (Beef) is inedible and prohibited for use as human food.

\* \* \* \* \*

Done at Washington, DC, on January 7, 2004.

Garry L. McKee,  
Administrator.

[FR Doc. 04-625 Filed 1-8-04; 1:43 pm]





UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

# FSIS NOTICE

5-04

1/12/04

## INTERIM GUIDANCE FOR NON-AMBULATORY DISABLED CATTLE AND AGE DETERMINATION

### I. PURPOSE

This FSIS notice provides Veterinary Medical Officers (VMOs) guidance for implementing new regulatory requirements regarding non-ambulatory disabled cattle and procedures for determining by dentition whether cattle are 30 months of age and older.

### II. BACKGROUND

FSIS issued three regulations and a notice in the Federal Register on January 12, 2004, in response to the diagnosis by USDA of a positive case of Bovine Spongiform Encephalopathy (BSE) in an adult Holstein cow in the State of Washington. These regulations and the notice will prevent human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease. This FSIS notice provides VMOs guidance in implementing the policy contained in docket #03-025IF ("Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle"), that non-ambulatory disabled cattle are unfit for human food. In addition, this FSIS notice provides VMOs guidance on distinguishing cattle 30 months of age and older from younger cattle. Although cattle of any age must have the tonsils and entire small intestine disposed of as inedible, cattle 30 months of age and older have additional specified risk materials (SRMs) that also may contain the BSE agent in cattle infected with the disease. These SRMs must be disposed of as inedible. Consequently, VMOs must verify that the carcasses and parts of cattle 30 months of age and older are properly identified and handled.

Among other requirements, the new regulations at 9 CFR 309.2(b) state that non-ambulatory disabled livestock, including cattle, are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column

**DISTRIBUTION:** Inspection Offices;  
T/A Inspectors; Plant Mgt; T/A Plant  
Mgt; TRA; ABB; TSC, Import Offices

**NOTICE EXPIRES:** 2/01/05

**OPI:** OPPD

or metabolic conditions. The new regulation at 9 CFR 309.3(e) states that non-ambulatory disabled cattle shall be condemned. Consequently, these cattle, which may be on the premise housing the slaughter establishment, cannot enter the slaughter establishment.

Non-ambulatory disabled cattle are considered unfit for use as human food. This determination is derived from Title 1, Section 1(m)(3) of the Federal Meat Inspection Act. Specifically,

*The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances: if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food*

Non-ambulatory disabled cattle remain subject to the provisions of the Humane Slaughter Act, its implementing regulations, and FSIS Directive 6900.1, Revision 1.

### **III. VMOs RESPONSIBILITIES REGARDING NON-AMBULATORY DISABLED CATTLE**

#### **A. What actions do VMOs take when non-ambulatory disabled cattle are presented for slaughter?**

1. The VMO is responsible for conducting ante-mortem inspection on all non-ambulatory disabled cattle, of any age, presented for slaughter. All non-ambulatory disabled cattle are to be U.S. condemned. VMOs also are to continue to condemn all cattle that are showing central nervous system (CNS) symptoms, even if the animal is ambulatory. Cattle condemned upon ante-mortem inspection cannot enter the slaughter establishment.

2. The VMO is to contact the Animal and Plant Health Inspection Service (APHIS) Area Veterinarian-in-Charge (AVIC) to allow APHIS the opportunity to collect BSE surveillance samples. APHIS is primarily interested in cattle that are 20 months of age and older and cattle showing signs of CNS disorder. Therefore, if cattle show signs of CNS disorder or are non-ambulatory disabled, and there is reason to believe that they are 20 months of age or older, VMOs are to make this known to the AVIC so the AVIC has an opportunity to collect a surveillance sample from the condemned animals.

a. If a sample is collected for the APHIS BSE Surveillance program from condemned cattle, VMOs are to ensure that all animal identification is maintained. The VMO should maintain control of the tested animal(s) until the establishment documents how the animal(s) will be properly disposed.

b. If the AVIC determines that it is not possible for APHIS personnel to get to the slaughter establishment, the AVIC will let the VMO know and the VMO is to proceed in verifying that the establishment properly disposes of the animal.

**B. What do VMOs verify regarding condemnation?**

1. VMOs are to verify that the establishment has properly disposed of animals in accordance with 9 CFR 309.13 and 9 CFR 314, and maintains the records required by 9 CFR 320. In the preamble to the new regulations contained in docket #03-0251F, FSIS recognizes activated charcoal as a proprietary substance approved by the Administrator that can be used for proper disposal in addition to the provisions at 9 CFR 314 for properly disposing of condemned carcasses.

2. At the request of the owner or operator, condemned cattle can be set apart and held for treatment (9 CFR 309.13(b)). Treatment is to be performed under the supervision of an FSIS program employee or designee of the District Manager. In addition, if cattle are to be released for a purpose other than slaughter (9 CFR 309.13(d)), the operator of the official establishment or the owner of the livestock must first obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction.

3. The VMO can inform the establishment that landfills are an acceptable option for disposal.

**C. What form do the VMOs use to document condemnation?**

VMOs are to complete condemnation certificates for cattle condemned on ante-mortem using FSIS Form 6000-13, Condemnation Certificates.

**D. What do VMOs do if cattle are ambulatory at ante-mortem inspection and become non-ambulatory disabled prior to slaughter? What is the disposition of the animal?**

If an otherwise normal healthy animal that has passed ante-mortem inspection and is on its way to the knock box and suffers an acute injury (e.g., if the animal falls or if an animal has a leg that gets trapped and broken), the VMO should verify that the animal suffered such an acute injury and allow the animal to proceed to slaughter and post-mortem inspection. FSIS would expect such situations to be extremely rare because cattle, when handled and moved under proper humane handling conditions, should not be injured while being moved in the pens. For cattle that become non-ambulatory disabled after ante-mortem inspection, if the VMO cannot determine that a specific, acute injury occurred that caused the animal to become non-ambulatory disabled, the animal is to be condemned and cannot enter the slaughter establishment.



**E. What is the responsibility of the Consumer Safety Inspection/Inspector-in-Charge in an official slaughter establishment where the VMO is not located on premise?**

If nonambulatory disabled cattle are presented for ante-mortem inspection, the CSI/IIC is to hold the animal until the VMO can arrive to perform ante-mortem on the animal and condemn it.

#### **IV. VMO RESPONSIBILITIES FOR AGE DETERMINATION**

A. VMOs are to examine establishment records that report the age of cattle because cattle 30 months of age and older contain additional SRMs beyond those for cattle of any age. The documentation may be in the form of:

1. a birth certificate,
2. cattle passport, or
3. some other form of identification that is presented with the animal when it arrives for slaughter

B. If VMOs conclude that the records are accurate and reliable, the records will be accepted as verification of the age of the cattle.

C. However, if VMOs examine the records and find significant reasons for questioning their validity, they are to verify the age of the cattle through dental examination.

D. VMOs are to consider cattle to be 30 months and older when the examination of the dentition of the animal shows that at least one of the second set of permanent incisors has erupted (see attachment). FSIS recognizes that the permanent incisors of cattle erupt from 24 through 30 months of age, but the Agency has determined that the described dentition procedure will be most protective of public health.

E. VMOs on patrol assignments are to correlate with inspection program personnel at slaughter establishments.

Direct questions to the Technical Service Center

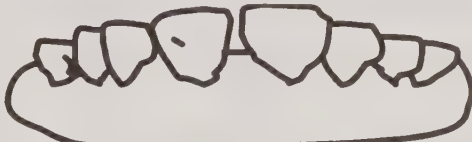
*/s/ Philip S. Derfler*

Assistant Administrator  
Office of Policy and Program Development

Attachment

The detention depicted below represents  
animals less than 30 months of age.

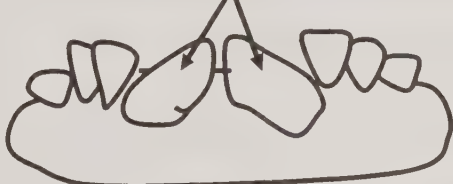
Full set of 8 temporary teeth  
on young calf.



Full set of 8 temporary teeth,  
at about 15 months of age



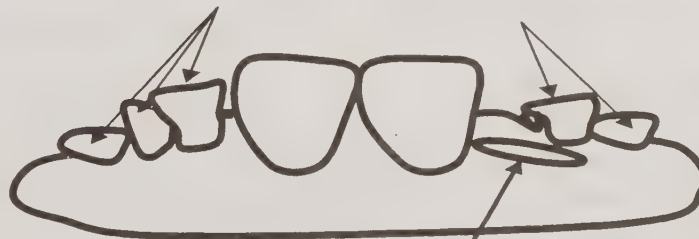
Erupting first set of permanent incisor.



Erupted first set of permanent incisor.



Temporary incisors



Erupting third permanent incisor, top  
of tooth **NOT** above gum line,  
animal less than 30 months of age.

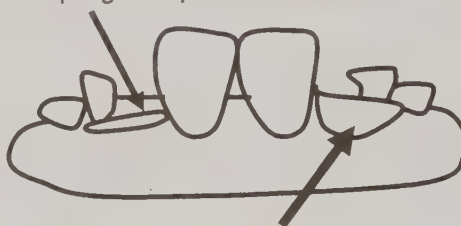
The dentition depicted below represents animals 30 months of age or older.

First set permanent incisors



Erupted third permanent incisor, top of tooth above gum line, animal 30 months of age.

Erupting forth permanent incisor.

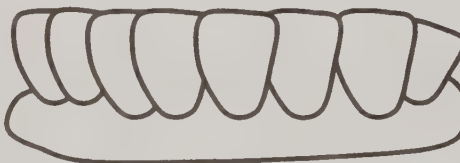


Erupted third permanent incisor (with top corners of the tooth above the gum line), animal 30 months of age or older.

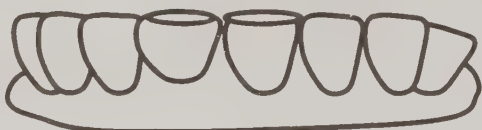


Four permanent incisor, (with top corners of the second set above the gum line), animal 30 months of age or older.

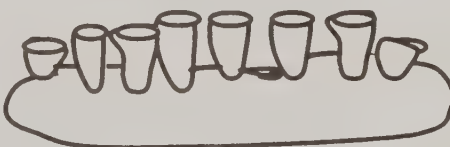
Full set of permanent incisors, animal over 48 months of age.



Age 72 months, medial incisors showing wear and leveled tops.



Age 120 months or older, permanent incisors showing wear and space between the teeth.





UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

FSIS NOTICE	10-04	1-29-04
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## QUESTIONS AND ANSWERS, REGARDING THE AGE DETERMINATION OF CATTLE AND SANITATION

### I. PURPOSE

The Agency is issuing this notice to clarify:

1. that documentation, rather than dentition, can be the primary means of determining the age of animals and to describe the types of documentation that have proven to provide an accurate and reliable basis for making this determination.
2. how inspection program personnel should verify that sanitation of equipment has been properly conducted when there is a possibility of contamination by specified risk materials (SRMs)

### PART I – Determination of the Age of Cattle

The age of cattle is determinative of which parts of cattle are SRMs as defined in 9 CFR 310.22. The guidance provided by the following questions and answers clarifies the types of records that an establishment may use to identify and to separate cattle that are younger than 30 months of age from cattle that are 30 months of age and older. VMOs are to conduct the procedures found in FSIS Notice 9-04 to verify that an establishment is following the procedures, as incorporated into its HACCP, Sanitation SOPs, or prerequisite program for determining the age of cattle.

Documentation, rather than dentition, provides the best means for determining the age of cattle. While dentition can be useful in the absence of documentation, it only provides a means of making general determinations about age. Documentation provides the means to specifically age the animals. Thus, establishments that separate cattle based on whether they are younger or older than 30 months of age may rely on documentation. This does not preclude the use of dentition if documentation is not available.

As set out in FSIS Notice 9-04, inspection program personnel are to verify that if an establishment separates cattle that are younger than 30 months of age from cattle that are 30 months of age and older it follows its procedures for identifying and separating the cattle and is making appropriate determinations.

While performing verification activities related to the age of cattle, inspection program personnel are to verify, in establishments using documentation, that the records support the establishment's determinations. If the records do not support the determinations, inspection program personnel are to verify that the establishment takes the appropriate corrective action under 9 CFR 417.3(a) or (b).

**NOTE:** Hands-on dentition examinations are not to be used to determine the adequacy of the documentation. If a VMO is unsure as to whether the plant's procedures are adequate, he or she is to contact the Technical Service Center for technical assistance.

While performing verification activities related to the age of cattle, inspection program personnel are to verify, in establishments using dentition, that the establishment's determinations are consistent with the guidance provide in FSIS 5-04. If the determinations made by the establishment are not consistent with the guidelines, inspection program personnel are to verify that the establishment takes the appropriate corrective action under 9 CFR 417.3(a) or (b).

## QUESTIONS AND ANSWERS

**Question:** What are the characteristics of documentation that have proven to be an accurate and reliable means for determining the age of cattle offered for slaughter?

**Answer:** The characteristics of documentation that is most useful in determining the age of cattle offered for slaughter are:

1. Documentation (e.g., records or certificates) that can be related to individual cattle and not just information about an entire lot, and
2. Documentation that provides evidence of age that goes back to the farm where the cattle were born, including the name and the address of the owner.

**Question:** What are examples of accurate and reliable documentation from the farm or ranch where the cattle were born?

**Answer:** The following are examples of farm or ranch documentation:

1. pregnancy check records (checks for individual cows and the results of the check for each one),
2. records of which cows were in a herd when a bull was put in with the herd, and when the bull was removed from the herd (to determine start of gestation),
3. records that document when individual cows were artificially inseminated,
4. calving records that document where (i.e., name and address of the producer) and when a calf was born, or
5. identification applied to calves (e.g., records from branding, electronic ear IDs, or ear tags).

**Question:** What are examples of accurate and reliable documentation from the feedlot where the cattle were held?

**Answer:** The following are examples of feedlot documentation:

1. Documentation that identifies the date that the cattle entered the feedlot and were given individual identification (e.g., eartags) and documentation that the producer provides with the

cattle as they enter feedlot that includes on-farm records, and

- i. the cattle have individual identification (e.g., eartags) that were placed on them on the farm, or
- ii. the entire herd of cattle are certified as being born on the farm during a specific range (e.g., certification that a group of Angus cattle were born during the calving season of Spring 200X or Fall 200X) and based on the information the feedlot identifies each animal individually (e.g., eartags).

**NOTE:** When calving birthing ranges are provided, the oldest possible age based on the ranges should be assigned to the group of cattle.

2. Medication records or worming records at the feedlot that tie back to when the animal was received by the feedlot and identify the producer. The feedlot could use these records to identify the producer, who then could state when the cattle were born.

## **PART II - Sanitation**

When an establishment is slaughtering or processing cattle 30 months and older and cattle younger than 30 months of age, what should inspection program personnel look for when verifying that the equipment (e.g., saws and knives) is properly cleaned and sanitized between carcasses or parts?

If **separate** equipment is used for cutting through SRMs **OR** if the establishment **segregates** the two age groups and slaughters or processes the younger group first, then routine operational sanitation procedures apply (in accordance with 9 CFR Part 416). For example:

- The establishment uses a dedicated saw to split the carcass from cattle 30 months and older.
- The establishment uses a knife to cut through the edible portions of the carcass and a separate saw to only cut through the vertebral column (e.g. when quartering a carcass).

Any equipment that is used to cut through SRMs (vertebral column, spinal cord, dorsal root ganglion, etc. of cattle 30 months and older) must be cleaned and sanitized before being used on carcasses or parts from cattle less than 30 months. For example:

- Splitting carcasses of mixed age groups in the slaughter department.
- Breaking quarters of mixed age groups into smaller portions in the fabrication department.
- A knife that is used to sever the head from the carcasses of mixed age groups.

**NOTE:** The equipment need not be cleaned to a pre-operational state before sanitizing. The organic materials must be removed to ensure adequate sanitization (this is similar to what is required when a saw cuts through an abscess).

For technical assistance contact the Technical Service Center.



*/s/ Philip S. Derfler*

Assistant Administrator  
Office of Policy and Program Development

<b>DISTRIBUTION:</b> Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices	<b>NOTICE EXPIRES:</b> 3/01/05	<b>OPI:</b> OPPD
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[Go Top](#)

**For Further Information Contact:**

Food Safety and Inspection Service  
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Telephone: 202-720-5627

Fax: 202-690-0486

E-mail: [FSIS.Regulations@fsis.usda.gov](mailto:FSIS.Regulations@fsis.usda.gov)

FSIS is in the process of developing a mechanism for electronic  
submittal of comments via e-mail – stay posted.

Send mail to [webmaster](#) with questions or comments about this web site.  
Last modified: January 30, 2004







# Specified Risk Materials



## Teaching Workshop

### Bovine Spongiform Encephalopathy (BSE)

#### Specified Risk Materials (SRMs)



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#### Specified Risk Materials (SRMs)

- On January 12, 2004, FSIS published an interim final rule on Specified Risk Materials (SRMs) and requirements for non-ambulatory disabled cattle.
  - SRMs only apply to cattle.
- Definition:
  - Specified Risk Materials are inedible and cannot be used in human food.

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#### SRM Requirements

- Apply to all beef plants:
  - Federal
  - State
  - Custom-Exempt
  - Imports

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### Specified Risk Materials (SRMs)

- In all cattle:
  - Tonsils
  - Distal ileum of the small intestine
    - Only the distal ileum is a Specified Risk Material, but the entire small intestine must be removed and not used for human food.

### Identifying Age of Cattle for Slaughter

- One of a plant's first activities should be to identify the age of cattle, because the SRMs are different for cattle 30 months of age and older.
  - If the plant does not have records on the age and is not using dentition, it should handle all carcasses and parts as if they were from cattle 30 months of age and older.

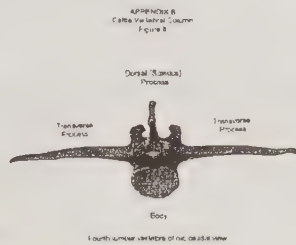
### SRMs – In cattle 30 months and older

- Brain
- Skull
- Eyes
- Trigeminal ganglia
- Spinal cord

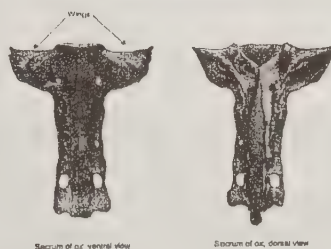


## SRMs – In cattle 30 months and older

- Dorsal root ganglia (DRG)
- Vertebral column, excluding
  - Vertebrae of the tail
  - Transverse process of the thoracic and lumbar vertebrae
  - Wings of the sacrum



Excerpted from  
Razum and Gussakov's  
The Anatomy of the Domestic Animals - Volume 1



Excerpted from  
Razum and Gussakov's  
The Anatomy of the Domestic Animals - Volume 1

### Reasons for Prohibiting these Parts

- It is generally accepted that in animals with clinical BSE disease, the brain and spinal cord contain the greatest concentration of the BSE agent.
  - Except for the skull and vertebral column, SRMs have demonstrated infectivity either in cattle naturally or experimentally.
  - The skull and vertebral column are included because they contain the trigeminal ganglia (skull) or the spinal cord and DRG (vertebral column).

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### SRMs – Plant Responsibilities

- Federal, State, and plants importing into the U.S. must:
  - Implement and maintain written procedures for the removal, segregation, and disposition of SRMs.
  - Incorporate these procedures into HACCP Plans, Sanitation SOPs or other prerequisite programs.
  - Have corrective action provisions.
- Custom-exempt plants:
  - Must comply with the adulteration provisions of the FMIA. (SRMs must be handled as inedible).

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### SRMs – Plant Responsibilities

- Plants must:
  - Maintain daily records to document implementation and monitoring of procedures for the removal, segregation, and disposition of SRMs.
  - Make these records available to FSIS inspection program personnel upon request.

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### Recommended Procedures

- If plants slaughter both young cattle and cattle 30 months and older:
  - Recommend that young cattle be slaughtered first
  - If cattle 30 months of age and older are slaughtered first, sanitize equipment and verify there is no cross-contamination of carcasses

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### Acceptable Procedures

- In cattle 30 months of age and older, after carcass-splitting:
  - Is acceptable to remove visible spinal cord with knife trimming.
  - To clean equipment, utilize the provisions of 9 CFR 416.

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### SRMs – Plant Responsibilities

- Processing plants must:
  - Segregate/identify bone-in product from cattle 30 months of age and older in order to properly address SRM removal and control.
  - Recognize that T-bone or porterhouse steaks and bone-in rib roasts can no longer come from cattle 30 months of age and older.

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	<p>disposition of SRMs.</p> <ul style="list-style-type: none"> <li>• Incorporate these procedures into HACCP plans, Sanitation SOPs or other prerequisite programs.</li> <li>• Have corrective action provisions.</li> <li>• Ensure that SRMs are completely removed from carcass, segregated from edible products, and appropriately disposed of.</li> <li>• Maintain daily records to document implementation and monitoring of procedures for the removal, segregation, and disposition of SRMs.</li> <li>• Make those records available to FSIS personnel upon request.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p>
<p><b>FSIS Responsibilities:</b></p> <ul style="list-style-type: none"> <li>• Normal inspection verification procedures for HACCP, Sanitation SOPs, and post-mortem inspection.</li> <li>• Verifying corrective actions.</li> </ul>	<p><b>FSIS Responsibilities:</b></p> <p><b>In addition to normal inspection procedures:</b></p> <ul style="list-style-type: none"> <li>• Ensure the adequacy and effectiveness of a plant's procedures.</li> <li>• Verify age of cattle by using a combination of procedures: <ul style="list-style-type: none"> <li>—Examine records that document age of cattle slaughtered in the plant.</li> <li>—Determine if at least one of the permanent incisors has erupted (which occurs at 24-30 months of age).</li> <li>—In plants which only process carcasses and parts, verify age through plant records.</li> <li>—If plant does not have the records, instruct it to handle all carcasses and parts as if from cattle 30 months of age and older.</li> </ul> </li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p> <ul style="list-style-type: none"> <li>• FSIS will develop compliance guidelines for small and very small plants to assist them in developing validated methods for meeting SRM requirements.</li> </ul>



## Prohibition of the Use of Specified Risk Materials for Human Food

New Regulatory Language	What it means
<p>PART 310—POST-MORTEM INSPECTION</p> <p>4. The authority citation for part 310 continues to read as follows: AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.</p> <p>5. A new § 310.22 is added to read as follows: § 310.22 Specified risk materials from cattle and their handling and disposition.</p> <p>(a) The following materials from cattle are specified risk materials:</p> <p>(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older;</p> <p>(2) The tonsils of all cattle; and</p> <p>(3) The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with §§ 314.1 or 314.3 of this subchapter.</p> <p>(b) Specified risk materials are inedible and shall not be used for human food.</p> <p>(c) Specified risk materials shall be disposed of in accordance with §§ 314.1 or 314.3 of this subchapter.</p> <p>(d) Procedures for the removal, segregation, and disposition of specified risk materials.</p> <p>(1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program.</p> <p>(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified</p>	<p>The following have been identified as specified risk materials from <b>all</b> cattle and are prohibited from use in human food:</p> <ul style="list-style-type: none"> <li>• Tonsils</li> <li>• Distal ileum (a part of the small intestine; in order to ensure that the distal ileum is appropriately disposed of, the entire small intestine is inedible; the distal ileum does not have to be removed from the small intestine for disposal)</li> </ul> <p>The following have been identified as specified risk materials from cattle that are 30 months of age or older and are prohibited from use in human food:</p> <ul style="list-style-type: none"> <li>• Brain</li> <li>• Skull</li> <li>• Eyes</li> <li>• Trigeminal ganglia (contained within the skull)</li> <li>• Spinal cord</li> <li>• Vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum)</li> <li>• Dorsal root ganglia (contained within the vertebral column)</li> </ul> <p>Specified risk materials must be disposed of according regulations prescribed in 314.1 or 314.3.</p> <p>Establishments that slaughter cattle must:</p> <ul style="list-style-type: none"> <li>• develop, implement and maintain written procedures for the removal, segregation and disposition of</li> </ul>

risk materials, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified risk materials in preventing the use of these materials for human food and shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) Recordkeeping requirements. (i)

Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section shall be retained for at least one year and shall be accessible to FSIS. All such records shall be maintained at the official establishment 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(e) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

specific risk materials. These procedures must be included in HACCP plans or in Sanitation SOP or other prerequisite programs.

- take corrective action when either the establishment or FSIS deems that the procedures are not effective in keeping specified risk materials out of human food.
- review and evaluate, on a routine basis, the effectiveness of their procedures for removal, segregation and disposition of specified risk materials, and make revisions to their procedures when necessary.
- keep daily records that document the implementation and monitoring of procedures for removal, segregation, and disposition of specified risk materials and any corrective actions that have been taken
  - records may be kept on establishment's computer that have appropriate controls to ensure integrity of electronic data
  - records will be kept for at least one year and accessible to FSIS
  - records shall be maintained by the establishment 48 hours after completion and may be maintained off-site but must be available to FSIS within 24 hours of request
  - records relate to specified risk materials from cattle 30 months of age or older at time of slaughter



New Regulatory Language	What it means
<p>PART 311-DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS</p> <p>6. The authority citation for part 311 continues to read as follows:  AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.</p> <p>7. Section 311.27 is amended as follows:</p> <p>a. By inserting “of all livestock except for cattle” in the first sentence after “the carcasses and all parts” and before “shall be kept for inspection”.</p> <p>b. By adding the following new sentence at the end of the paragraph: “The parts and carcasses of cattle slaughtered in the absence of an inspector shall not be used for human food.”</p>	<p>Part 311.27 no longer applies to cattle.</p> <p>An inspector must be present to perform ante-mortem and post-mortem inspection.</p>

New Regulatory Language	What it means
<p>PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS</p> <p>8. The authority citation for part 318 is amended to read as follows:  AUTHORITY: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.</p> <p>9. Section 318.6 is amended as follows:</p> <p>a. Paragraph (b)(1) is amended by removing the word “cattle” and adding the following new sentence at the end of the paragraph: “Casings from cattle may be used as containers of products provided the casings are not derived from the small intestine.”</p> <p>b. Paragraph (b)(4) is amended by adding the following new sentence at the end of the paragraph: “Detached spinal cords from cattle 30 months of age and older shall not be used as raw materials for edible rendering.”</p> <p>c. Paragraph (b)(8) is amended by adding the following new sentence at the end of the paragraph: “The small intestine of cattle shall not be used in any meat food products or for edible rendering.”</p>	<p>Small intestines from cattle cannot be used for product casings.</p> <p>Detached spinal cords from cattle that are 30 months of age or older can no longer be used for edible rendering.</p> <p>Small intestines can no longer be used in any meat food product or for edible rendering.</p>

New Regulatory Language	What it means
<p>10. The authority citation for part 319 continues to read as follows:  AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.</p> <p>11. Section 319.5 is amended as follows:</p> <p>a. A new paragraph (b) is added to read as follows:  § 319.5 Mechanically Separated Species.  * * * * *</p> <p>(b) Mechanically Separated (Beef) is inedible and prohibited for use as human food.</p> <p>b. Sections (c)-(d) are reserved.</p>	<p>The Agency is banning MS(beef) for use as human food. MS (beef) is not eligible to bear the mark of inspection.</p>

## Regulatory Changes

NOTE: The interim final rule which includes the preamble and these changes can be found in Tab 3 under Non-Ambulatory Disabled Cattle.

### Prohibition of the Use of Specified Risk Materials for Human Food And Requirements for the Disposition of Non-Ambulatory Disabled Cattle

#### List of Subjects

##### 9 CFR Part 309

Ante-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 310

Post-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 311

Post-mortem inspection, Disposition of carcasses.

##### 9 CFR Part 318

Entry into official establishments, reinspection and preparation of products.

##### 9 CFR Part 319

Food grades and standards, Food labeling, Meat inspection.

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For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

#### PART 309--ANTE-MORTEM INSPECTION

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1. The authority citation for part 309 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

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2. Paragraph (b) of Sec. 309.2 is revised to read as follows:

Sec. 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

\* \* \* \* \*

(b) All seriously crippled animals and non-ambulatory disabled

livestock shall be identified as U.S. Suspects and disposed of as provided in Sec. 311.1 of this subchapter unless they are required to be classed as condemned under Sec. 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

\* \* \* \* \*

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3. Section 309.3 is revised by adding a new paragraph (e) to read as follows:

Sec. 309.3 Dead, dying, disabled, or diseased and similar livestock.

\* \* \* \* \*

(e) Non-ambulatory disabled cattle shall be condemned and disposed of in accordance with Sec. 309.13.

#### PART 310--POST-MORTEM INSPECTION

0

4. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

0

5. A new Sec. 310.22 is added to read as follows:

Sec. 310.22 Specified risk materials from cattle and their handling and disposition.

(a) The following materials from cattle are specified risk materials:

(1) The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older;

(2) The tonsils of all cattle; and

(3) The distal ileum of all cattle. To ensure effective removal of the distal ileum, the establishment shall remove the entire small intestine, and shall dispose of it in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(b) Specified risk materials are inedible and shall not be used for human food.

(c) Specified risk materials shall be disposed of in accordance with Sec. Sec. 314.1 or 314.3 of this subchapter.

(d) Procedures for the removal, segregation, and disposition of specified risk materials.

(1) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials. The establishment shall incorporate such procedures into its HACCP plan or in its Sanitation SOP or other prerequisite program.



(2) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must take appropriate corrective action when either the establishment or FSIS determines that the establishment's procedures for the removal, segregation, and disposition of specified risk materials, or the implementation or maintenance of such procedures, have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and disposed of in accordance with paragraph (c) of this section.

(3) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall routinely evaluate the effectiveness of their procedures for the removal, segregation, and disposition of specified

[[Page 1874]]

risk materials in preventing the use of these materials for human food and shall revise the procedures as necessary whenever any changes occur that could affect the removal, segregation, and disposition of specified risk materials.

(4) Recordkeeping requirements. (i) Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the materials listed in paragraph (a) of this section, and any corrective actions taken.

(ii) Records required by this section may be maintained on computers provided that the establishment implements appropriate controls to ensure the integrity of the electronic data.

(iii) Records required by this section shall be retained for at least one year and shall be accessible to FSIS. All such records shall be maintained at the official establishment 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

(e) The materials listed in paragraph (a)(1) of this section will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter.

#### PART 311--DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

0

6. The authority citation for part 311 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

#### Sec. 311.27 [Amended]

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7. Section 311.27 is amended as follows:

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a. By inserting ``of all livestock except for cattle'' in the first sentence after ``the carcass and all parts'' and before ``shall be kept for inspection''.

0



b. By adding the following new sentence at the end of the paragraph:  
``The parts and carcasses of cattle slaughtered in the absence of an  
inspector shall not be used for human food.''

PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND  
PREPARATION OF PRODUCTS

0

8. The authority citation for part 318 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7  
CFR 2.18, 2.53.

Sec. 318.6 [Amended]

0

9. Section 318.6 is amended as follows:

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a. Paragraph (b)(1) is amended by removing the word ``cattle'' and  
adding the following new sentence at the end of the paragraph:  
``Casings from cattle may be used as containers of products provided  
the casings are not derived from the small intestine.''

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b. Paragraph (b)(4) is amended by adding the following new sentence at  
the end of the paragraph: ``Detached spinal cords from cattle 30 months  
of age and older shall not be used as raw materials for edible  
rendering.''

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c. Paragraph (b)(8) is amended by adding the following new sentence at  
the end of the paragraph: ``The small intestine of cattle shall not be  
used in any meat food products or for edible rendering.''

PART 319--DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

0

10. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR  
2.17, 2.55.

0

11. Section 319.5 is amended as follows:

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a. A new paragraph (b) is added to read as follows:

Sec. 319.5 Mechanically Separated Species.

\* \* \* \* \*

(b) Mechanically Separated (Beef) is inedible and prohibited for  
use as human food.

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

# FSIS NOTICE

9-04

1-23-04

## VERIFICATION INSTRUCTIONS FOR THE INTERIM FINAL RULE REGARDING SPECIFIED RISK MATERIALS (SRMs) IN CATTLE

### I. PURPOSE

This notice provides Veterinary Medical Officers (VMOs) with the methodology to use when verifying that an establishment has properly designed procedures to meet the requirements of 9 CFR 310.22 for the removal, segregation, and disposition of specified risk materials (SRMs). Also, this notice provides inspection program personnel with instructions for verifying that an establishment is executing its programs so that there is proper removal, segregation, and disposal of SRMs.

**NOTE:** At some establishments that do not slaughter but that process bone-in parts of cattle carcasses, an Enforcement Investigation Analysis Officer may be called upon to perform the verification of the design of the procedures in the absence of an available VMO.

### II. REGULATORY REQUIREMENTS

#### A. What are the regulatory requirements related to SRMs?

9 CFR 310.22(a) defines SRMs as:

(1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and

(2) the tonsils and the distal ileum (for which removal of the distal ileum must be achieved by disposing of the entire small intestine) of all cattle.

**DISTRIBUTION:** Inspection Offices;  
T/A Inspectors; Plant Mgt; T/A Plant  
Mgt; TRA; ABB; TSC, Import Offices

**NOTICE EXPIRES:** 2-01-05

**OPI:** OPPD

9 CFR 310.22(b) and (c) state that SRMs are inedible and shall not be used for human food and shall be disposed of in accordance with 9 CFR 314.1 and 314.3.

**B. What are establishments required to do in regard to SRMs?**

9 CFR 310.22 states that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures that are incorporated into their HACCP plan, or in their Sanitation SOP or other prerequisite program for the removal, segregation, and disposal of SRMs.

**III. VERIFICATION FOR THE DESIGN OF PROCEDURES FOR SRMs**

A. As described in FSIS Notice 4-04, VMOs are to verify that an establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of materials that present a risk of transmitting BSE.

B. VMOs are to verify into which programs (i.e., HACCP plans, Sanitation SOPs, or prerequisite programs) the establishment incorporated any procedures adopted as a result of its reassessment. All establishments may include their procedures in one or more of these programs.

1. If an establishment determines that SRMs are a hazard reasonably likely to occur in its process, VMOs are to verify that the establishment has designed controls and incorporated them into its HACCP plan in accordance with 9 CFR part 417.

2. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in its Sanitation SOPs, VMOs are to verify that the procedures and documentation supporting the establishment's determination are available for review under 9 CFR 416.14 and 417.5.

3. If an establishment determines that SRMs are not a hazard reasonably likely to occur because of procedures in a prerequisite program that the establishment has implemented, VMOs are to verify that the procedures and supporting documentation are available for review under 9 CFR 417.5.

C. VMOs should verify that the establishment has designed its monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to effectuate its HACCP plans, Sanitation SOPs, and other supporting prerequisite programs.

D. Examples of questions that may be asked to verify the design of the establishment's procedures to remove, segregate, and dispose of SRMs include:

1. Has the establishment adopted procedures designed to identify the cattle to be slaughtered that are 30 months of age and older?

**NOTE:** If the establishment identifies in its hazard analysis that all cattle will be considered 30 months of age and older, it is not necessary for the establishment to have evidence about the proof of the age of the cattle.



2. Has the establishment adopted procedures designed to ensure the complete and proper removal of SRMs?

3. Has the establishment adopted procedures designed to ensure that SRMs are segregated from edible product?

4. Has the establishment adopted procedures designed to ensure that SRMs are disposed of in a manner that will prevent cross-contamination with edible product?

**NOTE:** The vertebral columns from cattle 30 months of age and older do not have to be removed during the slaughter operation. However, if they are not removed in the slaughter operation, procedures should be put in place to ensure that the vertebral columns are adequately identified as being from cattle 30 months of age and older, and that the means of identification transfers with the vertebral columns until they are appropriately disposed of as inedible.

5. Has the establishment adopted control procedures designed either (1) to not allow bone-in beef from cattle 30 months of age and older into the establishment, or (2) to ensure that such product (e.g., vertebral columns for AMR) is handled in an appropriate manner (e.g., by ensuring that SRMs are removed and disposed of appropriately)? Has the establishment implemented verification measures to ensure that the control procedures are followed?

E. If an establishment has failed to reassess its hazard analysis, the VMOs should document in a decision memorandum to the District Office (DO) the evidence to support the issuance of a Notice of Intended Enforcement Action (NOIE).

#### **IV. VERIFICATION PROCEDURES FOR INSPECTION PROGRAM PERSONNEL**

A. Inspection program personnel are to verify the proper execution of the HACCP plans or the prerequisite programs, while conducting HACCP 01 or 02 procedures as set out in FSIS Directive 5000.1, Revision 1, or while verifying the effectiveness of Sanitation SOPs under 01B or 01C procedures. Inspection program personnel are to perform the verification activities related to SRM removal in conjunction with the other food safety concerns by reviewing records (e.g., looking at HACCP monitoring records), observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination), or by conducting hands-on inspection verification procedures (e.g., verify adequacy of Sanitation SOP procedures).

B. Inspection program personnel should verify that the establishment is conducting monitoring, verification, recordkeeping, and corrective actions, including reassessment as appropriate, to effectuate its HACCP plans, Sanitation SOPs, and other supporting prerequisite programs.

## **C. Post-mortem on-line verification duties**

### **Head and Carcass inspection:**

1. When on-line inspection program personnel perform individual carcass or head inspection and observe visible (readily identifiable) SRMs on edible portions of the product, the establishment may recondition the entire carcass or head by knife trimming.
2. On-line inspection program personnel are to notify the VMO or, if unavailable, other off-line inspection program personnel when there is evidence that an establishment's SRM control program is ineffective (for example, when repeated presentation of contaminated heads or carcasses for post-mortem inspection at the rail and head inspection station indicates failure to control SRM contamination).
3. The VMO or other off-line personnel will perform the appropriate HACCP or Sanitation SOP procedures to evaluate the process.

## **V. ENFORCEMENT**

What enforcement actions do inspection program personnel take when finding noncompliance?

If VMOs or off-line personnel determine the process failed to prevent SRMs from adulterating product, they are to issue a NR under the appropriate procedure code and mark the appropriate trend indicator as described in FSIS Directive 5000.1, Revision 1, Chapters I (Sanitation) II (HACCP) and IV (Enforcement) and verify that the establishment takes the corrective actions required by 9 CFR 417.3(a) or (b) or 416.15. If the procedures are under a prerequisite program, inspection program personnel are to verify that the establishment reassesses the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.

If the establishment does not properly implement procedures (e.g., recordkeeping), inspection program personnel are to issue a NR under the appropriate procedure code and mark the appropriate trend indicator as described in FSIS Directive 5000.1, Revision 1, Chapters I (Sanitation) II (HACCP) and IV (Enforcement) and verify that the establishment takes the immediate and further planned actions to correct the noncompliance.

Refer questions to the Technical Service Center.

*/s/ Philip S. Derfler*

Assistant Administrator  
Office of Policy and Program Development



Types of questions inspection program personnel may seek answers to while verifying that an establishment is properly executing its procedures to remove, segregate, and dispose of SRMs.

1. Is the establishment properly implementing its procedures to segregate animals 30 months of age and older?

**NOTE:** If the establishment identifies in its hazard analysis that all cattle will be considered 30 months of age and older, it is not necessary for the establishment to have evidence about the proof of the age of the cattle.

2. Is the establishment properly implementing its written procedures to remove, segregate, and dispose of SRMs?

3. Is the establishment cleaning and sanitizing equipment, (e.g., cleaning and sanitizing the splitting saw prior to use on cattle younger than 30 months if used after slaughtering cattle 30 months of age and older)?

4. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of SRMs?

5. Is the establishment including documentation with the shipped products identifying them as from cattle 30 months and older? Has it considered this step in its hazard analysis? Does it have procedures to ensure that the SRMs are removed at the receiving establishment?

6. Is the establishment routinely evaluating the effectiveness of their procedures for the removal, segregation, and disposition of SRMs in preventing the use of these materials for human food?

7. If an establishment determines that its process failed to remove SRMs, inspection program personnel are to verify that the establishment implements corrective actions in accordance with 9 CFR 417.3(a) or (b) (under HACCP), 9 CFR 416.15 (under Sanitation SOPs). If the procedures are under a prerequisite program, inspection program personnel are to verify that the establishment reassesses the HACCP plan to determine whether the decisions made in the hazard analysis continue to support the use of the prerequisite program.

8. Is the establishment taking appropriate immediate and further planned action when it identifies that it failed to properly implement its procedures (e.g., recordkeeping).







# BSE Surveillance





## Teaching Workshop

### Bovine Spongiform Encephalopathy (BSE)

#### BSE Surveillance



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## BSE Surveillance - Responsibilities

- The Animal and Plant Health Inspection Service (APHIS) has primary responsibility for BSE surveillance activities and the actual testing.
  - FSIS has responsibility to notify APHIS of opportunities for testing.
  - If a sample is taken, FSIS will no longer allow the mark of inspection to be applied until the result from the APHIS testing comes back negative.

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## New FSIS Requirements

- On January 12, 2004 FSIS issued two notices regarding our activities for BSE surveillance
  - The Bovine Spongiform Encephalopathy Surveillance Program (published in the *Federal Register*)
  - Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination (for FSIS inspection personnel)

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### Non-ambulatory Disabled Cattle

- Cannot be slaughtered
- Cannot enter the slaughter plant

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### FSIS VMO Responsibilities

- FSIS Veterinary Medical Officers (VMOs) conduct ante-mortem inspection on all abnormal cattle presented for slaughter.
- VMOs must condemn cattle which are:
  - Dead and dying.
  - Non-ambulatory disabled.
  - Show symptoms of central nervous system (CNS) disorders, even if ambulatory.

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### When VMOs Contact APHIS

- FSIS VMO contacts APHIS Area Veterinarian-in-Charge (AVIC) in these cases:
  - If cattle are non-ambulatory disabled,
  - If cattle show signs of CNS disorders,
  - And, if there is reason to believe such cattle are 20 months of age or older.

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### FSIS VMO Responsibilities

- If a sample is collected for the APHIS BSE Surveillance program, FSIS VMO:
  - Ensures that all animal identification is maintained.
  - Maintains control of the animal until the plant documents how it will properly dispose of the animal.

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### FSIS VMO Responsibilities

- The APHIS Veterinarian-in-Charge notifies the FSIS VMO if it is not possible for APHIS personnel to get to the slaughter plant.
- In that case, the FSIS VMO:
  - Maintains control of the animal until the plant documents proper disposal.
  - Ensures the animal is humanely euthanized.
  - Verifies disposal of the carcass.

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### FSIS VMO Responsibilities

- Verifies that the plant has properly disposed of the animals.
  - In accordance with 9 CFR 309.13 and 9 CFR 320.
- Maintains the records required by 9 CFR 320.
- Verifies rendering requirements met.
  - 9 CFR 309.13, 9 CFR 314.1 and 314.3

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### Condemned Cattle – Treatment

- At the request of the owner or operator, condemned cattle can be set apart and held for treatment. (9 CFR 309.13)
  - Treatment must be performed under the supervision of an FSIS program employee or designee of the District Manager.
  - The owner or operator must first obtain permission for the movement of such cattle from the local, State, or Federal livestock sanitary official having jurisdiction.

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### Further Information

- I urge you to review your workbooks. What I have discussed today is in:
  - FSIS Notice 5-04, Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination.
  - FSIS Notice published in the *Federal Register*, Bovine Spongiform Encephalopathy Surveillance Program.

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## Teaching Workshop

Bovine Spongiform Encephalopathy (BSE)

APHIS BSE Surveillance Program

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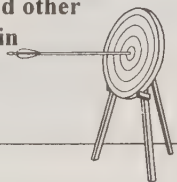
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### Targeted surveillance

- Non-ambulatory animals
- Dead stock
- Field CNS Cases and on-farm suspects
- Veterinary Diagnostic Laboratory data
- Public health laboratories
- CNS condemnments at slaughter and other antemortem condemnments in certain categories



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### Surveillance goals

- Surveillance at a level sufficient to find 1 case per 1 million adult cattle, 95% confidence
- Based on estimates of targeted high risk population
  - Non-ambulatory – 195,000
  - Broader estimate, including deads and other condemnments – 600,000
- Adult cattle population – 45 million

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### Surveillance goals

- Estimate high risk population
  - FSIS condemnns (CNS, emaciation, tetanus, deads, injuries, moribund) – 194,225
  - CNS on farm FAD's – 129
  - Dead on farm of unknown causes (NAHMS, NASS estimates) – 340,000
- Total – 534,354
- Rounded total estimate = 600,000

### Surveillance goals

- FY 02 and FY 03 – goal was 12,500
  - Based on estimate of non-ambulatory animals as targeted population (195,000)
- FY 04 – goal is at least 40,000
  - Based on broader estimate of targeted population (600,000)
  - Statistical calculation is 38,462 samples necessary, rounded up to 40,000

### Surveillance: US Regions



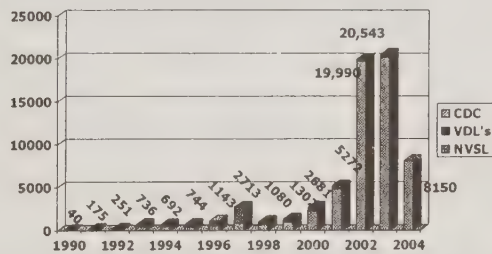
## US Regional Goals

### BSE Surveillance (through 12/31/03)

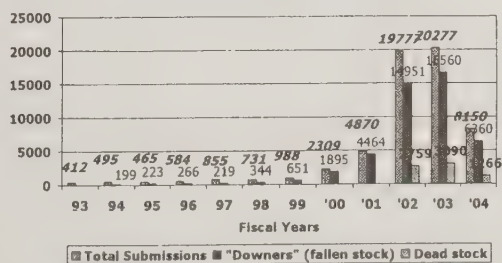
	FY01 Goal	FY01	FY02 Goal	FY02	FY03 Goal	FY03	FY04 Goal	FY04
NW	564	695	1,205	2,224	1,205	781	4832	489
SW	466	564	1,976	2,753	1,976	3,645	4172	470
C	766	332	1,590	2,356	1,590	2,628	6640	1403
SC	734	872	1,509	1,810	1,509	1,690	6380	1251
NC	606	620	2,561	3,780	2,561	5,620	5180	1990
NE	462	805	2,140	2,190	2,140	2,595	3912	1004
E	312	401	363	1,381	363	514	2644	507
SE	644	953	1,005	3,156	1,005	2,800	5580	1030

## BSE Surveillance: Yearly totals

May 1990 – FY 2004 (thru 12/31/2003)



## Surveillance: NVSL Bovine Brain Submissions FY 93-04 (through 12/31/03)



### Adjustments to U.S. BSE Surveillance?

- Our surveillance objective remains the same
- Have taken an even more conservative approach by re-evaluating the size of our at-risk population and increasing the number sampled
- Bulk of the sampling still dead and non-ambulatory animals (on farm, renderers, pet food plants)
- Will adjust geographic sampling distributions if needed



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### What are we asking of FSIS?

- Call APHIS-Veterinary Services if you condemn an adult animal ante-mortem for CNS signs – as requested in the past
- Call APHIS-Veterinary Services if you condemn an adult animal ante-mortem for non-ambulatory disabled.

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## Bovine Spongiform Encephalopathy (BSE) Surveillance Program and Holding Procedures

### Previous Requirements Before January 12, 2004

### Current Requirements Beginning January 12, 2004

<p><b>Situation:</b></p> <ul style="list-style-type: none"> <li>No BSE positives had been found in the U.S.</li> </ul>	<p><b>Situation:</b></p> <ul style="list-style-type: none"> <li>The first BSE positive for a cow in the U.S. was confirmed on December 25, 2003.</li> </ul>
<p><b>Testing for BSE:</b> Animal and Plant Health Inspection Service (APHIS) tested cattle for BSE:</p> <ul style="list-style-type: none"> <li>Cattle that FSIS personnel condemned because they showed possible symptoms of BSE.</li> <li>This included non-ambulatory disabled cattle, which were allowed to be slaughtered in certain cases.</li> <li>Random samples from brains of cattle that appeared to be healthy (surveillance).</li> </ul>	<p><b>Testing for BSE:</b> Animal and Plant Health Inspection Service (APHIS) tests cattle for BSE:</p> <ul style="list-style-type: none"> <li>Cattle that FSIS personnel condemn because they show possible symptoms of BSE.</li> <li>FSIS no longer allows non-ambulatory disabled cattle to be slaughtered. The owner is responsible for having the animal humanely euthanized. APHIS will sample the carcass for BSE at an inedible rendering facility.</li> <li>APHIS will continue BSE surveillance and testing at an increased rate.</li> <li>APHIS veterinarians send samples to USDA's National Veterinary Services Laboratories.</li> </ul> <p>(A notice was published on January 12, 2004.)</p>
<p><b>Inspection procedures – FSIS:</b></p> <ul style="list-style-type: none"> <li>“Inspected and passed” mark of inspection applied to carcasses and parts from cattle that were selected for testing by APHIS for BSE, before the results were received.</li> <li>Recommended that plants hold carcasses until test results were received.</li> </ul>	<p><b>Inspection procedures – FSIS:</b></p> <ul style="list-style-type: none"> <li>“Inspected and passed” mark of inspection will <u>not</u> be applied to carcasses and parts from cattle that are selected for testing by APHIS for BSE.</li> <li>Is developing a Directive to instruct inspection program personnel on procedures.</li> </ul> <p>(A notice was published on January 12, 2004.)</p>





[Federal Register: January 12, 2004 (Volume 69, Number 7)]

[Notices]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 03-048N]

Bovine Spongiform Encephalopathy Surveillance Program

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

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SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it will no longer pass and apply the mark of inspection to the carcasses and parts from cattle that are selected for testing by USDA's Animal and Plant Health Inspection Service (APHIS) for Bovine Spongiform Encephalopathy (BSE) until the sample is determined to be negative.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Office of Policy and Program Development, Food Safety and Inspection Service, 1400 Independence Avenue SW., Washington, DC 20250-3700; (202) 205-0495.

SUPPLEMENTARY INFORMATION: The mission of the U.S. Department of Agriculture (USDA) is to enhance the quality of life for the American people by ensuring a safe, affordable, nutritious, and accessible food supply. APHIS is responsible for ensuring animals and plant health. FSIS is responsible for protecting the Nation's meat, poultry, and egg products supply, making sure it is safe, wholesome, not adulterated, and properly labeled and packaged. These two agencies lead USDA's program activities for prevention, monitoring, and control of bovine spongiform encephalopathy (BSE) in cattle and in the U.S. food supply. BSE, widely referred to as "mad-cow disease," is a chronic degenerative disease affecting the central nervous system (CNS) of cattle.

To prevent the entry into commerce of meat and meat food products that are adulterated, FSIS inspection program personnel perform ante- and post-mortem inspection of cattle that are slaughtered in the United States. As part of the ante-mortem inspection, FSIS inspection program personnel look for symptoms of disease, including signs of CNS



``Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

Done at Washington, DC on January 7, 2004.  
Garry L. McKee,  
Administrator.  
[FR Doc. 04-627 Filed 1-8-04; 1:43 pm]









# Advanced Meat Recovery (AMR)



## Teaching Workshop

### Bovine Spongiform Encephalopathy (BSE)

#### Advanced Meat Recovery (AMR)



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## New Requirements for AMR—Beef

- On January 12, 2004, FSIS published:
  - 3 interim final rules with requests for comments and one notice.
  - In response to the December 25, 2003 confirmed positive of BSE in a cow in the U.S.
- One rule added new requirements for AMR.

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## Advanced Meat Recovery (AMR)

- AMR systems:
  - Enable processors to remove attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone product into the final meat product.
  - When used properly, the product from AMR systems is comparable to meat derived by hand deboning.

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### Advanced Meat Recovery (AMR)

- AMR systems
  - Use hydraulic pressure to emulate the physical action of hand-held high-speed knives to remove skeletal muscle tissue from bone.
  - Application of pressure detaches meat from the bones in a "hard separation" process.

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### Harvard Risk Assessment for BSE

- USDA commissioned the Harvard Center for Risk Analysis to conduct a risk assessment for BSE:
  - Indicated that the most important means by which low-risk tissue can become contaminated is through the use of AMR systems that can leave spinal cord and dorsal root ganglia (DRG) in the recovered meat product.

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### FSIS 2002 Survey of AMR Products

- For seven months, FSIS collected samples from AMR systems that used beef vertebrae as source material.
  - Tested for the presence of spinal cord and DRG.
  - Only 12% of plants were able to produce final AMR product with no spinal cord or DRG on a consistent basis.

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### Prohibited from Use in AMR

- As of January 12, 2004, meat derived from AMR systems cannot contain the following parts from any livestock:
  - Brain
  - Spinal cord
  - Dorsal root ganglia (DRG)
  - Trigeminal ganglia
  - Significant amounts of bone solids or marrow

### Prohibited from Use in AMR

- In addition, for cattle 30 months of age and older:
  - Skulls and vertebral column bones are prohibited from use in AMR systems.

### New AMR Requirements

- To ensure that AMR systems are not a means of introducing central nervous system (CNS)-type tissue into product labeled as "meat".
- In addition, FSIS has determined MS(Beef) to be inedible and prohibits it from use as human food.

### Plant Responsibilities – AMR Beef

- In addition to meeting all existing regulatory requirements, plants which produce AMR beef must:
  - Reassess their hazard analysis to determine if there is a hazard reasonably likely to occur.
    - AMR regulatory changes are likely to affect the hazard analysis.

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### Plant Responsibilities – AMR Beef

- Ensure that the AMR production process is in control in order to prevent the introduction of central nervous system (CNS)-type tissue into product labeled as "meat".
- Have these control procedures and recordkeeping included in the HACCP plan, Sanitation SOP, or other prerequisite program.

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### Plant Responsibilities – AMR Beef

- Maintain records on the entire AMR process control system on a daily basis.
  - Previously, recordkeeping requirements applied only to the calcium criteria.
- Make those records available to FSIS inspection program personnel upon request.

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### Plant Responsibilities – AMR Beef

- Observe bones entering the AMR system.
- Test product exiting the AMR system.
- Determine how and when the plant will test AMR product for calcium, iron, spinal cord, and DRG.
  - May use testing methods which are not as sensitive as the method FSIS uses, but are less expensive.

### AMR from All Livestock

- AMR from livestock other than cattle must also meet the new requirements.
- Only differences:
  - There are no Specified Risk Materials (SRMs) for other livestock.
  - HACCP plan does not have to be reassessed, but the program must be documented in writing.

### FSIS Responsibilities

- In addition to present inspection procedures, inspection program personnel will:
  - Take samples from plants which produce AMR products, to ensure that prohibited tissues are not in the product.
  - Verify plant testing, using validated histological procedures.

### FSIS Responsibilities

- FSIS is developing inspection procedures, and methodology, including those for sampling and testing.

### Enforcement

- If a plant's AMR system repeatedly fails to produce product free of prohibited materials, it will not be allowed to produce AMR meat from vertebrae.



## Food Safety and Inspection Service (FSIS) Requirements for Advanced Meat Recovery (AMR) – Beef

Advanced Meat Recovery (AMR) is an industry technology that removes muscle and other edible tissue from the bone of beef carcasses under high pressure without incorporating bone. The machinery separates meat by scraping, shaving or pressing the muscle and edible tissue away from the bones. Bones must emerge essentially intact and in their natural shape. Under Food Safety and Inspection Service (FSIS) regulations, AMR product can be labeled as “meat.”

Because BSE was confirmed in a cow in the United States on December 25, 2003, FSIS developed an emergency interim final rule to ensure that AMR systems are not a means of introducing Central Nervous System (CNS) type tissues into the food supply.

Previous Requirements Before January 12, 2004	Current Requirements Beginning January 12, 2004
<p><b>Prohibited from use in AMR:</b> Spinal cord ( FSIS Directive 7160.3 Revision 1, 8/25/03)</p>	<p><b>Prohibited from use in AMR:</b> From all cattle:</p> <ul style="list-style-type: none"> <li>• Brain,</li> <li>• Spinal cord,</li> <li>• Dorsal root ganglia (DRG), Trigeminal ganglia, and</li> <li>• Significant amounts of bone solids or marrow.</li> </ul> <p>From cattle 30 months of age or older,</p> <ul style="list-style-type: none"> <li>• Skull and</li> <li>• Vertebral column bones.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p>
<p><b>If a plant’s AMR system repeatedly fails:</b> Plants whose AMR system repeatedly failed to produce product free of spinal cord were no longer allowed to produce AMR meat from beef vertebrae. ( FSIS Directive 7160.3 Revision 1, 8/25/03)</p>	<p><b>If a plant’s AMR system repeatedly fails:</b> Plants whose AMR system repeatedly fails to produce product free of these parts will not be allowed to produce AMR meat from beef vertebrae.</p>
<p><b>Plant Responsibilities:</b> Meet all regulatory requirements, including:</p> <ul style="list-style-type: none"> <li>• Development and implementation of Hazard Analysis and Critical Control Points (HACCP) Plan and Sanitation Standard Operating Procedures (SOPs).</li> <li>• Kept records only on the calcium criteria.</li> </ul> <p>( FSIS Directive 7160.3 Revision 1, 8/25/03)</p>	<p><b>Plant Responsibilities:</b> Meet all regulatory requirements, including:</p> <ul style="list-style-type: none"> <li>• Development and implementation of Hazard Analysis and Critical Control Points (HACCP) Plan and Sanitation Standard Operating Procedures (SOPs).</li> <li>• Reassess hazard analysis to determine if there is a hazard reasonably likely to</li> </ul>

	<p>occur. AMR regulatory changes are likely to affect hazard analysis.</p> <ul style="list-style-type: none"> <li>• Ensure that their AMR production process is in control.</li> <li>• Have control procedures and recordkeeping in HACCP plan, Sanitation SOP, or other prerequisite program.</li> <li>• Observe bones entering AMR system.</li> <li>• Test product exiting AMR system.</li> <li>• Maintain records on entire AMR process control system, on a daily basis.</li> <li>• Make those records available to FSIS personnel upon request.</li> <li>• Determine how and when the plant will test product for calcium, iron, spinal cord, and DRG.</li> <li>• May use testing methods which are not as sensitive as the method FSIS uses, but less expensive.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p>
<p><b>FSIS Responsibilities:</b>  <b>In addition to normal inspection procedures, Inspection Personnel:</b></p> <ul style="list-style-type: none"> <li>• Took samples from plants to ensure that spinal cord tissue was not in AMR product.</li> <li>• Randomly collected a single composite sample (two pounds) produced from cattle which were 30 months of age or older.</li> <li>• Notified plant management and allowed them to hold the AMR products from sampled production until the results became available.</li> </ul> <p><b>If the sample tested positive, FSIS:</b></p> <ul style="list-style-type: none"> <li>• Issued the plant a Noncompliance Record (NR),</li> <li>• Took control of any product produced by the system tested on the day of the sampling.</li> <li>• Took control of AMR system equipment.</li> <li>• Verified that the plant properly disposed of the product.</li> </ul>	<p><b>FSIS Responsibilities:</b>  <b>In addition to normal inspection procedures, Inspection Personnel:</b></p> <ul style="list-style-type: none"> <li>• Take samples from plants which produce AMR products, to ensure that prohibited tissues are not in the product.</li> <li>• Verify plant testing, using validated histological procedures.</li> <li>• Specific inspection procedures, including those for sampling and testing, are being developed. This includes disposition of product which is found positive for specific materials.</li> </ul> <p>(Interim was final rule and request for comments published January 12, 2004.)</p>

- |   |  |
|---|--|
| <ul style="list-style-type: none"><li>• Requested a recall of any AMR product, or product containing AMR, produced on the day of sampling and shipped.</li></ul> <p><b>Follow-up to a Positive:</b></p> <ul style="list-style-type: none"><li>• Inspection personnel verified plant's corrective and preventive actions and collected 10 follow-up composite samples.</li><li>• From the results, FSIS determined whether or not the plant's AMR system was in control.</li></ul> <p>( FSIS Directive 7160.3 Revision 1, 8/25/03)</p> |  |
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## Food Safety and Inspection Service (FSIS) Requirements for Advanced Meat Recovery (AMR) – Pork

Advanced Meat Recovery (AMR) is an industry technology that removes muscle and other edible tissue from the bone of livestock carcasses under high pressure without incorporating bone. The machinery separates meat by scraping, shaving or pressing the muscle and edible tissue away from the bones. Bones must emerge essentially intact and in their natural shape. Under Food Safety and Inspection Service (FSIS) regulations, AMR product is labeled as “meat,” but must have the species listed.

Because BSE was confirmed in a cow in the United States on December 25, 2003, FSIS developed an emergency interim final rule to ensure that AMR systems are not a means of introducing Central Nervous System (CNS) type tissues into the food supply.

FSIS is applying the new requirements to pork as well as beef. FSIS has initiated a survey on pork AMR products and believes that the lack of process control for CNS-type tissues in pork product recovered from AMR systems may also be a concern. However, concerns about AMR pork are primarily a about labeling rather than food safety.

### Previous Requirements Before January 12, 2004

### Current Requirements Beginning January 12, 2004

<p><b>Prohibited from use in AMR:</b> Spinal cord ( FSIS Directive 7160.3 Revision 1, 8/25/03)</p>	<p><b>Prohibited from use in AMR:</b></p> <ul style="list-style-type: none"> <li>• Spinal cord,</li> <li>• Brain,</li> <li>• Dorsal root ganglia (DRG),</li> <li>• Trigeminal ganglia, and</li> <li>• Significant amounts of bone solids or marrow.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p>
<p><b>Plant Responsibilities:</b> Meet all regulatory requirements, including:</p> <ul style="list-style-type: none"> <li>• Development and implementation of Hazard Analysis and Critical Control Points (HACCP) Plan and Sanitation Standard Operating Procedures (SOPs).</li> <li>• Kept records only on the calcium criteria. ( FSIS Directive 7160.3 Revision 1, 8/25/03)</li> </ul>	<p><b>Plant Responsibilities:</b> Meet all regulatory requirements, including:</p> <ul style="list-style-type: none"> <li>• Development and implementation of Hazard Analysis and Critical Control Points (HACCP) Plan and Sanitation Standard Operating Procedures (SOPs).</li> <li>• Reassess hazard analysis to determine if there is a hazard reasonably likely to occur.</li> <li>• Ensure that their AMR production process is in control.</li> <li>• Have control procedures and recordkeeping in HACCP plan,</li> </ul>



	<p>Sanitation SOP, or other prerequisite program.</p> <ul style="list-style-type: none"> <li>• Observe bones entering AMR system.</li> <li>• Test product exiting AMR system.</li> <li>• Maintain records on entire AMR process control system, on a daily basis.</li> <li>• Make those records available to FSIS personnel upon request.</li> <li>• Determine how and when the plant will test product for calcium, iron, spinal cord, and DRG.</li> <li>• May use testing methods which are not as sensitive as the method FSIS uses, but less expensive.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p>
<p><b>FSIS Responsibilities:</b>  <b>In addition to normal inspection procedures, Inspection Personnel:</b></p> <ul style="list-style-type: none"> <li>• Took samples from plants to ensure that spinal cord tissue was not in AMR product.</li> <li>• Randomly collected a single composite sample (two pounds) produced from cattle which were 30 months of age or older.</li> <li>• Notified plant management and allowed them to hold the AMR products from sampled production until the results became available.</li> </ul> <p><b>If the sample tested positive, FSIS:</b></p> <ul style="list-style-type: none"> <li>• Issued the plant a Noncompliance Record (NR),</li> <li>• Took control of any product produced by the system tested on the day of the sampling.</li> <li>• Took control of AMR system equipment.</li> <li>• Verified that the plant properly disposed of the product.</li> <li>• Requested a recall of any AMR product, or product containing AMR, produced on the day of sampling and shipped.</li> </ul> <p><b>Follow-up to a Positive:</b></p> <ul style="list-style-type: none"> <li>• Inspection personnel verified plant's</li> </ul>	<p><b>FSIS Responsibilities:</b>  <b>In addition to normal inspection procedures, Inspection Personnel:</b></p> <ul style="list-style-type: none"> <li>• Take samples from plants which produce AMR products, to ensure that prohibited tissues are not in the product.</li> <li>• Verify plant testing, using validated histological procedures.</li> <li>• Specific inspection procedures, including those for sampling and testing, are being developed. This includes disposition of product which is found positive for specific materials.</li> </ul> <p>(Interim final rule and request for comments was published January 12, 2004.)</p>



<p>corrective and preventive actions and collected 10 follow-up composite samples.</p> <ul style="list-style-type: none"><li>• From the results, FSIS determined whether or not the plant's AMR system was in control.</li></ul> <p>( FSIS Directive 7160.3 Revision 1, 8/25/03)</p>	
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## Regulatory Changes

NOTE: The interim final rule which includes the preamble and these changes follows this section.

Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems

### List of Subjects

#### 9 CFR Part 301

Meat and meat products.

#### 9 CFR Part 318

Meat inspection, Records.

#### 9 CFR Part 320

Meat inspection, Records.

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For the reasons set forth above, FSIS is amending 9 CFR, chapter III, as follows:

### PART 301--TERMINOLOGY

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1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

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2. In Sec. 301.2, the definition of ``Meat'' is revised to read as follows:

#### Sec. 301.2 Definitions.

\* \* \* \* \*

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of



brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).  
\* \* \* \* \*

PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND  
PREPARATION OF PRODUCTS

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3. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7  
CFR 2.7, 2.18, and 2.53.

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4. Section 318.24 is revised to read as follows:

Sec. 318.24 Product prepared using advanced meat/bone separation  
machinery; process control.

(a) General. Meat, as defined in Sec. 301.2 of this subchapter,  
may be derived by mechanically separating skeletal muscle tissue from  
the bones of livestock, other than skulls or vertebral column bones of  
cattle 30 months of age and older as provided in Sec. 310.22 of this  
subchapter, using advances in mechanical meat/bone separation machinery  
(i.e., AMR systems) that, in accordance with this section, recover  
meat--

(1) Without significant incorporation of bone solids or bone marrow  
as measured by the presence of calcium and iron in excess of the  
requirements in this section, and

(2) Without the presence of any brain, trigeminal ganglia, spinal  
cord, or dorsal root ganglia (DRG).

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(b) Process control. As a prerequisite to labeling or using product  
as meat derived by the mechanical separation of skeletal muscle tissue  
from livestock bones, the operator of an establishment must develop,  
implement, and maintain procedures that ensure that the establishment's  
production process is in control.

(1) The production process is not in control if the skulls entering  
the AMR system contain any brain or trigeminal ganglia tissue, if the  
vertebral column bones entering the AMR system contain any spinal cord,  
if the recovered product fails otherwise under any provision of  
paragraph (c)(1), if the product is not properly labeled under the  
provisions of paragraph (c)(2), or if the spent bone materials are not  
properly handled under the provisions of paragraph (c)(3) of this  
section.

(2) The establishment must document its production process controls  
in writing. The program must be designed to ensure the on-going  
effectiveness of the process controls. If the establishment processes  
cattle, the program must be in its HACCP plan, its Sanitation SOP, or  
other prerequisite program. The program shall describe the on-going  
verification activities that will be performed, including the  
observation of the bones entering the AMR system for brain, trigeminal  
ganglia, and spinal cord; the testing of the product exiting the AMR  
system for bone solids, bone marrow, spinal cord, and DRG as prescribed





in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these activities will be performed.

(3) The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process.

(4) The establishment shall make available to inspection program personnel the documentation described in paragraphs (b)(2) and (b)(3) of this section and any other data generated using these procedures.

(c) Noncomplying product. (1) Notwithstanding any other provision of this section, product that is recovered using advanced meat/bone separation machinery is not meat under any one or more of the following circumstances:

(i) Bone solids. The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 130.0 mg per 100 g.

(ii) Bone marrow. The product's added iron content, measured by duplicate analyses on individual samples and rounded to the nearest 10th, is more than 3.5 mg per 100 g.\1\  
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\1\ The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100 g measured and rounded to the nearest 100th or more for that sample, minus the product of three factors: (1) The iron to protein ratio (IPR) factor associated with corresponding hand-deboned product; (2) the obtained protein (P) result (%) for that sample; and (3) a constant factor of 1.10. In formula, this can be written as:  $ExcFe = mFe - IPR \times Protein \times 1.10$ , where ExcFe represents the excess iron, expressed in units of mg/100 g; mFe represents the measured level of iron (Fe, mg/100 g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and ``Protein'' is the measured level of protein rounded to the nearest 100th and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.  
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(iii) Brain or trigeminal ganglia. Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.

(iv) Spinal cord. Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.

(v) DRG. The product that exits the AMR system contains DRG.

(2) If product that may not be labeled or used as ``meat'' under



this section meets the requirements of Sec. 319.5 of this subchapter, it may bear the name ``Mechanically Separated (Species)'' except as follows:

(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR system shall not be used as an ingredient of a meat food product.

(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.

(iii) If product derived from any bones of cattle of any age does not comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name ``Mechanically Separated (Beef).''

(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.

#### PART 320--RECORDS, REGISTRATION AND REPORTING

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5. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, and 2.53.

#### Sec. 320.1 [Amended]

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6. Section 320.1, paragraph (b)(10), is amended by removing ``of calcium content in meat derived from'' and adding, in its place, ``documenting the development, implementation, and maintenance of procedures for the control of the production process using.''

\* \* \*



comments will be available for inspection in the FSIS Docket Room or on the FSIS Web site at <http://www.fsis.usda.gov>.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0495.

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Background

The mission of the Food Safety and Inspection Service (FSIS) is to ensure that meat and meat food products are wholesome, not adulterated, and properly marked, labeled and packaged. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FSIS has the authority to determine that product is unfit for human food, i.e., adulterated, within the meaning of section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). Furthermore, a meat or meat food product is misbranded under any of a number of circumstances, including if its labeling is false or misleading in any particular; if it is offered for sale under the name of another food; if it is an imitation of another food, unless its label bears (in type of uniform size and prominence) the word "imitation" and, immediately thereafter, the name of the food imitated; or if it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by regulations, unless it conforms to the regulations and its label bears the name of the food specified in the definition and standard (21 U.S.C. 601(n)(1), (n)(2), (n)(3), and (n)(7)). This interim final rule addresses both the adulteration and misbranding provisions of the FMIA.

BSE

Bovine Spongiform Encephalopathy (BSE) is a slowly progressive degenerative disease that affects the central nervous system (CNS) of adult cattle and is a member of the family of diseases known as transmissible spongiform encephalopathies (TSEs). TSEs also include scrapie in sheep and goats, chronic wasting disease in elk and deer, and variant Creutzfeldt-Jakob Disease (vCJD) in humans.

The typical incubation period (the time from when an animal becomes infected until it first shows signs of disease) is believed to be from two to eight years. BSE was first documented in the United Kingdom in





1986, and has since been identified and confirmed in a number of other European and non-European nations.

The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein, although other types of agents have been implicated. FSIS has determined that this interim final rule is necessary to ensure that AMR systems are not a means of introducing CNS-type tissues (including brain, trigeminal ganglia, spinal cord, and dorsal root ganglia (DRG)), which have been identified as a potential source for the BSE infective agent into the food supply.

#### Animal Age and BSE Infectivity

Age-of-onset was known and recorded for approximately 135,000 cattle with confirmed clinical BSE in the United Kingdom between 1988 and August 2003. The age distribution data show that, of the cattle that developed clinical BSE in the field, only 0.01 percent were less than 30 months of age. Therefore, cattle younger than 30 months of age are less likely to be in the later stages of BSE incubation than older BSE-infected cattle and are less likely to contain high levels of BSE infectivity. For additional information about the onset of clinical BSE, see the interim final rule "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disable Cattle," Docket No. 03-025IF, also in this issue of the Federal Register.

FSIS is providing a method for its inspection program personnel in slaughter establishments to use to determine the age of cattle when supporting documentation is not provided by the establishment. This is relevant to this rulemaking on advanced meat/bone separation machinery and meat recovery (AMR) systems because AMR systems generally are operated separate from slaughter operations. Thus, establishments will need to process skulls and vertebral columns under control programs (i.e., Hazard Analysis Critical Control Point (HACCP) plans, Sanitation Standard Operation Procedures (Sanitation SOPs), or prerequisite programs) separate from their slaughter operation controls. To ensure that the skulls and vertebral columns are appropriately handled, the slaughter establishment will need to provide documentation associated with the age of the skulls and vertebral columns to the receiving processing operation. Establishments using AMR systems will need to ensure that the skulls and vertebral columns are not from cattle 30 months of age and older.

#### Infective Tissue

In 2001, the European Commission's Scientific Steering Committee (SSC), an advisory committee for the European Union, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1 percent of the total infectivity in the animal, and the spinal cord contains 25.6 percent. According to the SSC, the highest remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG (3.8 percent). In experimentally infected cattle with clinical BSE, infectivity has been demonstrated in the brain, spinal cord, DRG, trigeminal ganglia, and the distal ileum of the small intestine. For additional information about BSE infectivity, see Docket No. 03-025IF.



#### The Harvard BSE Risk Assessment

In 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the current measures implemented by the government to prevent the introduction and spread of BSE in the United States and to reduce the potential exposure of consumers to the BSE agent.

Using a probabilistic simulation model to characterize the consequences of introducing BSE into the country through a variety of pathways, the Harvard study concluded that the risk to consumers in the United States was low, and that the country is highly resistant to the spread of the disease, if introduced.\1\

In evaluating the potential risk mitigation actions that could be taken to further reduce the likelihood that BSE could spread to cattle or humans, the risk assessment recommended three courses of action. The first is to prevent infected or potentially infected animals or contaminated feed from entering the country. The second is to ensure compliance with Food and Drug Administration's (FDA's) ruminant feed ban. The third is to prohibit the infective materials of BSE-infected animals from entering both the human food and animal feed chains.

The Harvard study divided potential sources of human exposure to BSE infectivity into two categories: Specific high-risk tissues and contamination of low-risk tissues. The former include, in order of infectivity, brain, spinal cord, DRG, distal ileum, trigeminal ganglia, and other tissues found in the head (e.g., eyes and tonsils). As for the latter, the Harvard study indicated that the most important means by which low-risk tissue can become contaminated is through the use of AMR systems that can leave spinal cord and DRG in the recovered meat product.

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#### The AMR Process

AMR systems are newer models of systems that have been used since the 1960s. The new systems emulate the physical action of hand-held high-speed knives for the removal of skeletal muscle tissue from bone through the use of hydraulic pressure. AMR systems apply pressure to detach the meat (skeletal muscle) tissue from the bones in a ``hard separation'' process. Desinewers that typically use belt pressure against a rotating perforated steel drum then separate meat from connective tissue, sinews, and other non-meat components in a ``soft separation'' process. In addition to vertebrae, typical bones processed by piston-driven AMR systems are brisket bones (breast or lower chest), rib bones, flat bones (scapulas), and hip bones (pelvis).

AMR product is an intermediate product that is typically blended at about 5 to 12 percent of the formulation of ground products derived from manufacturing trimmings. Descriptive labeling for the product of AMR includes ``(species) trimmings, finely textured,''' ``finely ground (species),''' or any other term that accurately reflects its form.

AMR technology enables processors to remove attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product. When produced properly, product from AMR systems is comparable to meat derived by hand deboning and can be labeled as ``meat'' (9 CFR 301.2). Under the FSIS regulations, spinal cord is not a component of meat, and



therefore, product from AMR systems identified as ``meat'' that contains spinal cord is misbranded. Until today, FSIS has not taken regulatory action against ``meat'' containing DRG and other CNS-type tissues.

From January through August 2002, FSIS conducted a survey of AMR products derived from the vertebral column of cattle to establish a baseline for the prevalence of spinal cord and DRG in beef AMR products (referred to as the 2002 Beef AMR Survey). In the 2002 Beef AMR Survey, the Agency found that while some establishments were able to consistently produce beef AMR product that was free of spinal cord and DRG, a majority of the establishments had difficulty keeping spinal cord and DRG out of their AMR products. Overall, FSIS found that that approximately 76% (25 of 34) of the establishments whose AMR product was tested had positive laboratory results for spinal cord, DRG, or both in their final beef AMR products. The survey also found that approximately 35% (89 of 256) of all final AMR product samples that were tested had positive laboratory results for spinal cord, DRG, or both.

In March 2003, after completion of the 2002 Beef AMR Survey, FSIS implemented a routine regulatory sampling program of beef products from AMR systems as an additional measure to prevent misbranding of beef AMR products. Prior to the implementation of this regulatory sampling program, FSIS inspection program personnel collected AMR product samples for analysis for the presence of spinal cord tissue only if they believed that the establishment was not completely removing spinal cord from the vertebral column before the vertebral bones entered the AMR system (FSIS Directive 7160.2, April 14, 1997). Under the revised regulatory sampling program, FSIS inspection program personnel take samples of beef AMR product on a routine basis to verify that spinal cord tissue is not present in such product (FSIS Directive 7160.03, Revision 1, August 25, 2003). If spinal cord tissue is detected in beef AMR product, FSIS inspection program personnel take regulatory control action against the AMR product and equipment to prevent misbranded product from entering commerce. If the establishment has distributed misbranded beef AMR product, FSIS requests a voluntary recall.

Removal of the spinal cord before the vertebral columns enter the AMR system does not always ensure that spinal cord or DRG will not be incorporated into the final product. The Harvard study (discussed below) found that, if a beef carcass is mis-split when the spinal cord is removed, a portion of the spinal cord may remain encapsulated in the spinal canal of the vertebral column, and, if it is not removed before the vertebral bones enter the AMR system, the spinal cord could contaminate the final AMR product. Even when the spinal cord is completely removed from the vertebral column, the DRG of cattle are firmly attached to the bones of the vertebral column and are not removed along with the spinal cord. Thus, removing the spinal cord from the vertebral column does not prevent the DRG from entering an AMR system and becoming incorporated into the final AMR product.

Although FSIS and the regulated industry have recently taken actions to prevent the incorporation of spinal cord and, in some instances, DRG, in beef AMR products, FSIS continues to detect spinal cord and DRG in its routine regulatory sampling of beef AMR products, although to a lesser extent than it did in the 2002 Beef AMR Survey. In its routine regulatory sampling conducted from March to December in 2003, FSIS found spinal cord in 23 of 340 randomly scheduled samples, an estimated prevalence of 6.8 percent. In addition, the prevalence in follow-up samples was 13.6 percent, indicating that establishments with







an initial positive continued to have some problems controlling for spinal cord in beef AMR systems. While FSIS was testing samples for spinal cord, FSIS also recorded the results for DRG. The prevalence for DRG was found in 10.9 percent of the samples in which DRG was recorded.\2\

Under the current regulations, AMR product that contains DRG, or any other CNS tissue except spinal cord, is not misbranded and can be identified as meat. However, given the nature of DRG and other CNS tissue except spinal cord, and the fact that BSE has been confirmed in a cow in the United States, FSIS has reconsidered its approach to the presence of all CNS tissues, particularly from cattle, as further discussed below. In addition, for a more complete explanation as to why skulls and vertebral columns of cattle 30 months of age and older are designated as specified risk materials (SRMs) and cannot be used in AMR systems, see Docket No. 03-025IF in this issue of the Federal Register.

In addition to the measures identified to address BSE through restrictions associated with SRMs, FSIS also is identifying additional measures to restrict the use of beef product and spent bone materials associated with CNS-type tissues from cattle younger than 30 months of age, as described below. Finally, FSIS is finalizing new bone solids and bone marrow restrictions that are slightly modified from those previously proposed for livestock product labeled as ``meat.''

#### Previous Rulemaking

In 1994, the Agency published a final rule (59 FR 62551) to amend the definition of ``meat'' to include product resulting from AMR systems. The 1994 rule reflected the Agency's position that calcium limits and the physical conformation of the bones exiting the system were sufficient to ensure that the production process was in control, and that the characteristics and composition of the resulting product were those of meat.

The rule required that product resulting from the bone separation process not exceed a calcium content of 0.15 percent or 150 milligrams/100

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grams of product (150 mg/100 g) within a tolerance of 0.03 percent or 30 mg/100 g of product for each sample analyzed. The rule also required that the bones emerging from the AMR machinery be comparable to those resulting from hand deboning; that is, they must be essentially intact and in their natural physical conformation, such that they are recognizable as, for example, loin bones and rib bones, when they emerge from the machinery.

Shortly after FSIS issued the 1994 rule, consumer groups expressed concern that the regulatory requirements for meat produced by AMR systems were not being met consistently. Consumer groups alleged that, in certain AMR operations, the starting materials and machinery were being manipulated to produce a product that conformed to the requirements for Mechanically Separated (Species) (MS(Species)), a finely comminuted meat food product that may include spinal cord and dorsal root ganglia (DRG), but not to the requirements for meat. (At the time, FSIS considered spinal cord to be central nervous system (CNS) tissue. However, FSIS did not include DRG within the meaning of CNS tissue. Rather, it considered DRG to be more a part of the peripheral nervous system instead of a CNS-type tissue because it was



contained within the nexus between the spinal cord and the muscle tissue.)

In 1995, FSIS conducted a survey of federally inspected meat establishments using AMR systems. Inspection program personnel in 13 of the 48 surveyed establishments reported results that were not in compliance with the requirements for AMR established in the 1994 rule.\3\

To determine whether the product that was being produced by AMR systems was compositionally consistent with hand-deboned meat, in 1996, FSIS began conducting a survey to profile the chemical and histological composition of meat derived from beef neck bones. Beef neck bones from the upper vertebral column are split during the slaughter dressing process, as opposed to long bones which generally are not split, and thus are inherently likely to contribute bone content (e.g., marrow) to the product resulting from the AMR system. Samples were found to contain spinal cord and fragments of other CNS-type tissue. FSIS concluded that the AMR product produced was likely not comparable to corresponding hand-deboned product, even when the calcium criterion of the 1994 rule was for the most part met.

The results of the 1996 survey demonstrated that the provisions of the 1994 rule, if met, were not sufficient to ensure that AMR product would be comparable to hand-deboned meat in composition. A final report on the 1996 survey results is available in the Docket Room and on the FSIS web site.\4\

After considering information from consumer groups about compliance concerns, reviewing the 1995 field survey and the response to a 1996 notice soliciting public comment on that survey, and studying the results of the 1996 neck bone survey, FSIS concluded that it was necessary to propose amending its regulations and to issue a directive to inspection personnel to ensure that manufacturers were not incorporating spinal cord into AMR product labeled as meat. In 1997, FSIS published Directive 7160.2 to instruct inspection program personnel that establishments must completely remove spinal cord from any neck or back bones before the bones enter the AMR system. The directive emphasized that the definition of ``meat'' in 9 CFR 301.2 does not apply when the use of AMR systems results in product that contains spinal cord. FSIS did not address DRG in the directive because, at that time, FSIS did not have validated methodology to identify DRG, and DRG was not yet identified as a potential risk material.

On April 13, 1998, FSIS issued a proposed rule (63 FR 17959), in which it stated that provisions in the 1994 final rule needed revision to prevent misbranding and economic adulteration of AMR product labeled as ``meat.'' Specifically the Agency proposed to: (1) Adopt performance standards for bone solids and bone marrow; (2) adopt a zero tolerance for the presence of spinal cord; and (3) delete the provision that focused upon the condition of the bones emerging from the AMR systems to determine whether or not the production process was in control. The Agency's objective was to ensure that the regulations provided clear standards for industry to meet.

Prior to December 23, 2003, FSIS had not addressed AMR systems in the context of BSE, although FSIS had taken numerous steps to limit the presence of spinal cord in product derived from AMR systems. In particular, in March 2003, FSIS announced the results of the 2002 Beef AMR Survey and stated that FSIS soon would clarify its intent by rulemaking on AMR to ensure that DRG was excluded from the definition of product labeled as ``meat.''



By 2002, FSIS had a validated methodology to detect and discern DRG, there was widespread agreement within the scientific community that DRG was included within the meaning of CNS-type tissue, and there was scientific evidence that DRG carried the BSE infective agent. FSIS did not contemplate addressing tissues of brain and trigeminal ganglia in product from AMR systems because FSIS was not aware of any establishments using bone material, such as skulls, that would contain these tissues in the production of meat. Brain and trigeminal ganglia, along with spinal cord and DRG, all fit within the meaning of CNS-type tissues for purposes of further discussion in this document. Currently, FSIS does not analyze meat for tissues of brain and trigeminal ganglia. However, since skulls may in the future be used in AMR systems, FSIS is reassessing whether it should validate its testing methodology to detect and discern brain and trigeminal ganglia in product recovered from AMR systems.

FSIS has concluded that the 1994 rule, the 1998 proposed rule, and the FSIS Directives will not keep spinal cord and other CNS-type tissue out of product derived from livestock, particularly cattle, that is labeled as ``meat.'' FSIS concludes that restrictions for CNS-type tissues need to be explicitly stated in the regulations, along with a requirement to have written process control procedures and testing by the establishment, to ensure that the process control procedures are effective in producing product labeled as ``meat.''

Furthermore, FSIS has initiated a survey on pork AMR products and believes that the lack of process control regarding the presence of CNS-type tissues in pork product recovered from AMR systems also may be a concern. The new requirements in this interim final rule are applicable, for the most part, to products derived from pork bones.

FSIS has decided to publish this new AMR regulation as an interim final rule and to address both CNS-type tissues and the restrictions related to bone solids and bone marrow. The presence of spinal cord or other CNS-type tissue in AMR product, that is, in meat, particularly from cattle, represents a potential threat to the public health of the United States. The Administrator thus finds that there is good cause to make this new AMR regulation effective immediately. It is especially designed to prevent the occurrence of spinal cord and other CNS-type tissues in ``meat'' and meat food products derived from cattle, and to prevent the occurrence of spinal cord and other CNS-type tissues in ``meat'' derived from livestock other than cattle.

Before explaining in more detail the provisions of this interim final rule, a

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brief discussion of the comments received on the proposal and FSIS' responses follows.

#### Discussion of Public Comments on Docket 96-027P

The 60-day comment period on the 1998 proposed AMR rule ended on June 12, 1998. Forty-five comments were received from food and equipment manufacturers, professional and industrial trade associations, consumers and consumer advocacy organizations, academia, and consultants.

On December 16, 1999, FSIS issued a notice (64 FR 70200) reopening the comment period for an additional 30 days to give the public an opportunity to review and comment on the methods and results used by







Agricultural Research Service (ARS) scientists to derive new iron-to-protein values. The Agency also sought comment on a report submitted by a meat industry group regarding economic and worker safety issues relevant to the proposed rule. The reopened comment period closed on January 18, 2000. Twenty-six additional comments were received in response to the notice. The two sets of comments and FSIS' responses are merged in this ``Comment'' section.

#### Bone Solids

Comment: Many commenters disagreed with the proposed calcium requirement that was established as a measure of the bone solids content of AMR product, to ensure that AMR product is meat. One commenter stated that the limit was too high, and another suggested that the limit should be lowered to approximate the calcium level in hand-deboned meat, with a reasonable allowance for variation. Another commenter pointed out that FSIS asserted in the 1994 final rule that its purpose was to ensure that the characteristics and composition of AMR are consistent with those of meat. Another commenter claimed that the proposed reduction in the calcium level was arbitrary and determined on the basis of a limited data set and not based on actual process data. Another commenter requested that the calcium performance standard account for differences among meat species.

Response: FSIS does not agree that the calcium standard should be based only on actual process data and does not agree that the calcium level for AMR products needs to approximate that of hand-deboned products. The calcium level in hand-deboned products is nearly negligible. The increased amount in the AMR product that the Agency proposed to allow represented a small amount of calcium that would not in any appreciable way affect the safety or quality of the product. When the vertebrae are split, increased bone dust (i.e., material high in calcium) is created and may accumulate in the AMR product. In hand-deboning, such material is less likely to be incorporated into the product. The calcium limit that FSIS proposed was based on the results of its 1996 survey and the data that were submitted to FSIS by industry. FSIS believes that this calcium limit can be consistently achieved by industry and represents a more appropriate level than that in the 1994 rule.

Regarding the comment about different calcium levels for beef and pork, FSIS considered data for different species that were submitted by industry groups as well as the data gathered by FSIS in the 1996 survey. A summary of the data is presented in the technical addendum, which is available in the Docket Room and on the FSIS web page. The data show that average calcium levels for AMR pork and beef products are approximately 100 mg/100 g. FSIS believes that these data suggest that with regard to bone solids, there would not be any significant difference between pork and beef. Therefore, the required calcium targets for pork and beef AMR products are the same in this interim final rule.

As mentioned above, in 1994, FSIS believed that the performance standards it established regarding calcium as a measure of bone solids content, and the physical conformation of the bones exiting the system were sufficient to ensure that the AMR production process was in control, and that the characteristics and composition of the resulting AMR product would be comparable to those of meat. However, based on the results of the 1996 AMR survey, FSIS concluded that the established performance standards, even if met, were not sufficient to ensure that



AMR product would be comparable to meat and as a consequence proposed different standards in 1998. In particular, regarding compositional parameters, the 1996 results showed that the AMR products produced at the time were not comparable to hand-deboned product with respect to a number of measures, even when the calcium limit designed to measure bone solids content was met.

The 1998 proposed rule identified a calcium limit of 130 mg/100 g product. This level was premised on a target average level of approximately 100 mg/100 g product but did not specify whether the 130 mg/100 g was an average or an absolute level. Data collected by the Agency and submitted by industry indicated that the average calcium level obtained for AMR pork and beef products is approximately 100 mg/100 g, but that there was wide variation in individual establishment results. Furthermore, the average of the calcium results in the 2002 Beef AMR Survey was below 100 mg/100 g, but again, there was wide variation in individual results.

FSIS is clarifying in this interim final rule that no analysis can exceed the regulatory maximum of 130 mg/100 g sample. This level of calcium in the product does not affect the appearance, texture, or other quality aspects of the product and is a small amount of calcium when compared to the calcium content generally contained in MS(Species).

In deciding on a calcium level, FSIS understands that it is virtually impossible for calcium levels in AMR product to be equal to those of hand-deboned product, which is essentially 0 mg/100 g. The presence of small amounts of calcium does not affect the qualitative characteristics of the product and only trivially affect its compositional aspects. Thus the standard will ensure that AMR product is "meat." In addition, this standard creates a clear distinction between AMR product and MS(Species) product, which generally has more than triple the calcium of AMR. At the same time, FSIS has tried not to set such a low level for calcium that it would not be economically feasible to produce AMR product.

Comment: A commenter thought that calcium samples should be taken at the intermediate stage of the AMR process, because at this stage the calcium samples would indicate whether bones are being broken or crushed.

Response: FSIS is only concerned about the levels of calcium in the final AMR product as a means of ensuring that an excess amount of bone solids is not introduced into the product. It is not using a calcium measurement level to determine if bones are broken or crushed. Thus, FSIS is not including a standard to measure calcium at an intermediate stage in the AMR process in this interim final rule.

#### Bone Marrow

Comment: Commenters stated that the methodology and data used to derive the iron criterion that was proposed as a measure for noncomplying product were incorrect, and that, therefore, the proposed values were not appropriate. Specifically, it was pointed out that the analytical procedures used in the FSIS 1996 survey were based on procedures that understated iron values. Further, a commenter disagreed with the Agency's

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approach of correlating histological data and the bone marrow cell





assessment, with iron content. The commenter claimed that the correlation was not high, and thus was not accurate.

A commenter agreed that a measurement of total iron is a good indicator of the presence of marrow in meat and further claimed that the amount of iron in beef is well established. However, there were many comments that questioned both using excess iron as a measure of bone marrow and the methodology used to establish the limit in the standard. A commenter suggested not using protein at all in adjusting the iron requirement but, rather, using a straight iron value level. A commenter suggested that FSIS needs to account for the fact that AMR procedures remove connective tissue that contains little or no iron, and that muscle adjacent to the bone is higher in iron than is hand-deboned muscle. Therefore, even if marrow components were absent, iron-to-protein ratios (IPRs) would be higher in AMR products than those in hand-deboned meat.

Another commenter claimed that the use of iron as proposed by the Agency would be biased against low fat, high protein products and suggested a simple IPR. Some commenters said that the iron levels established were too high and urged FSIS to make the target levels more consistent with hand-deboned product. These commenters suggested a 5 to 10 percent variation in the IPR between AMR and hand-deboned meat. Commenters also suggested that establishments should not be permitted to determine their own IPR values, as was proposed.

Response: FSIS will first address the measurement and methodology issue and then provide a justification for the excess iron measure it proposed. In the course of doing so, it will provide an explanation for the procedures that it used for deriving the iron performance standard contained in this interim final rule.

Excess iron is the iron in excess of that which would be expected given the protein value if the product was meat. The measure for excess iron for the 2002 survey was:  $\text{excFe} = \text{Fe} - kP$ , where P is the protein (%), Fe is the iron (mg per 100 g), and k is a constant equal to 1.1 times 0.138. The 0.138 is the assumed IPR for the corresponding hand-deboned meat product, and the 1.1 is an adjustment factor.

Measurement and methodology. While the measurement used by FSIS was accurate, the Agency agrees that the methodology and measurement procedures used in developing the standards for iron in the 1998 proposed rule were not consistent with common laboratory analyses for iron measurement. FSIS used a hydrochloric acid wet-ash digestion procedure to measure the iron levels of samples collected in the 1996 survey because this methodology was considered faster and less labor intensive than traditional dry-ash procedures (i.e., dry-ash procedure for digestion). The wet-ash procedure predictably underestimates the true level of iron. In contrast, the method used by ARS scientists, which is based on a dry-ash procedure for digestion, dries the samples and obtains iron results approximately double those obtained by the FSIS procedure. Further, the results obtained by the ARS dry-ash procedure are more consistent with levels previously reported for hand-deboned product in Agricultural Handbook 8 (now called USDA Nutrient Database for Standard Reference, Release 12).

ARS analyzed split samples from the 1996 survey for FSIS, and FSIS used the ARS results along with more current FSIS data for deriving the standards for iron in this interim final rule. For samples in which there were no dry-ash procedure results, the FSIS wet-ash procedure results were multiplied by 2.11, which is the average ratio of the results from the dry-ash procedure to those that FSIS found using the hydrochloric acid wet-ash procedure (See the technical addendum for





additional information in the FSIS docket room and on the web site).\5\

FSIS agrees with the commenter's concern about FSIS' approach of correlating histological data and bone marrow cells with iron content and thus is not including a standard for bone marrow cells in this interim final rule. Although bone marrow cells are unique to bone marrow, they have been found in hand-deboned product probably as a consequence of contamination of the muscle tissue during the carcass splitting process during slaughter.

FSIS justification for using excess iron as a measure of bone marrow. FSIS has determined that there is no practical methodology to measure bone marrow using commercial practices. Bone marrow contains many of the same components as muscle tissue and blood. Therefore, FSIS sought to establish in the 1998 proposal a practical methodology that would predict whether the known composition of hand-deboned meat was sufficiently different from AMR as a consequence of the incorporation of bone content (other than calcium) in AMR. FSIS deemed this additional bone content to be an indication of the presence of bone marrow. Consequently, iron, which is contained in marrow and in blood tissue, was chosen as a practical surrogate for bone marrow.

To determine whether there were excess iron levels in AMR, and thus bone marrow in this product, the Agency proposed using an adjustment based on the protein value because an analysis of the data from a prior survey demonstrated that there was a correlation between iron and protein results. Protein levels will change with iron levels, everything else being equal. If bone marrow, which has a higher IPR value than meat, is added to product, the measured IPR value would be greater than the IPR for corresponding hand-deboned product without bone marrow. Accounting for measurement error, if this difference is large enough, it can then be concluded that bone marrow at more than a negligible amount is in the product.

One of the commenters pointed out that a problem with the above model is that the AMR process removes connective tissue that contains little or no iron. The Agency believes that the effect of this removal is not large and would not change the basic premise of the model presented above. From the 1996 FSIS survey, the Agency determined that the average difference in protein between pre- and post-desinewed AMR product was about 0.5 percent, based on a post-desinewed product average protein of about 16.5 percent. Therefore, as a percentage of protein, the amount of protein associated with connective tissue removed during the desinewing step averaged only about 3 percent and does not represent a large proportion of the protein that is in the final product.

In addition, it is possible that, during AMR processing, some unbound water is removed which would result in the removal of some water-soluble protein and dissolved solids).\6\

FSIS recognizes that these two factors, removal of connective tissue with low iron and protein and removal of unbound water, may result in an increase in the IPRs of AMR product. However, FSIS does not believe that such a possible increase renders the use of an excess iron measurement inaccurate for assessing AMR process control. Although FSIS does not believe that the effects of these factors would be substantial, it has taken them into consideration in this interim final rule and is using a 10 percent factor for adjusting the protein levels used for calculating levels of excess iron in AMR product.

Another issue raised by the commenters regarding the appropriateness of the excess iron



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measurement was that meat close to the bone has higher IPRs than meat farther from the bone. FSIS agrees with the commenter. However, the IPRs would be expected to be higher in AMR product than in hand-deboned product, even though no bone marrow would be introduced.

FSIS has decided to allow alternative IPRs to be used in this interim final rule to reflect the inherent differences that exist among starting products.

Regarding the comment made that the use of the excessive iron measure as proposed would be biased against high protein and low fat products, FSIS believes that for practical purposes, the difference between the excessive iron and the IPR calculations is not great.

In this interim final rule, however, FSIS is adopting a different excess iron limit measurement than the one proposed in 1998. This new limit is based on a more current examination of excess iron measurements for hand-deboned product from the 2002 survey of AMR product. See footnote 1 in new Sec. 318.24(c)(1)(ii) for a detailed explanation of the formula derived for the excess iron value measurement.

An assumption used by FSIS in the derivation of the excess iron value measurement for this interim final rule was that there would be duplicate measurements of iron and protein taken by establishments on an individual sample. Performing duplicate measurements on an individual sample is recommended because, on a few occasions in the 2002 survey, large differences for samples were found when duplicate measurements were made. Thus, to ensure that AMR product is consistent with meat, FSIS is adopting a measured 3.5 mg/100 g excess iron limit based on duplicate analyses of samples of AMR product.

#### Related Comments

Comment: Several commenters alleged that FSIS has singled out AMR technology for scrutiny while products derived from a low temperature rendering process (LTRP) were approved by FSIS for the school lunch program without any scientific basis or public input. The suggestion was made that FSIS withdraw the proposed rule on AMR products until comparable rules to regulate LTRP products have been developed and implemented.

Response: The Agency has focused on meat produced by AMR systems because it is the main product not produced by hand-deboning, and is a product in which constituents not expected in boneless meat can be incorporated as a result of the process used for its production. Other technologies, such as LTRP, generally involve the removal of components such as fat and muscle. The Agency intends to further evaluate how it regulates other types of operations that are used to manufacture meat and poultry trimmings from various starting materials. The Agency seeks more specific comment and data on the compositional characteristics of LTRP and similar products derived from non-AMR systems.

Comment: A commenter said the proposal was based on an antiquated regulatory foundation because the definition of meat is obsolete and is, in effect, an anatomical description. In addition, the commenter maintained that the proposal was an attempt to relate a chemical constituent of AMR-derived product to the former USDA Handbook 8 references for regulatory purposes and conflicted with Agency policies regarding constituents of other meat products.

Response: Meat is defined in anatomical terms, and not chemically,





because it is directly obtained from livestock and not chemically derived from other elements. Therefore, the regulatory definition of meat refers to the parts of livestock that are edible (as opposed to inedible parts/organs). The former Handbook 8 details the composition of foods but does not represent a formula for making ``meat.'' FSIS is not relating a constituent of AMR product to former Handbook 8 data on the composition of meat. AMR product is meat unless it includes constituents such as spinal cord and DRG that are not expected constituents of boneless meat. In addition, FSIS has determined that AMR product is meat unless the process by which it is produced incorporates expected constituents, such as calcium and iron, at excessive levels.

Comment: A commenter asked about FSIS' response to the report on AMR technology and on worker safety issues related to AMR systems.\7\

Response: Regarding the report, which was produced by the Georgetown University Center for Food and Nutritional Policy, FSIS generally agrees with the historical and technical aspects of the report on AMR systems. The report addressed the disagreements that have characterized the regulated introduction of mechanical deboning in this country, and how these initiatives have attracted the attention of consumer advocacy groups. The 1999 report states that the presence of CNS tissue in meats of any kind should be avoided and cited FSIS' prohibition against spinal cord in AMR meat since 1997.

The report discussed the reduction in worker-related injuries as perhaps the greatest societal advantage of AMR systems. FSIS agrees that manual deboning and the use of motorized knives are dangerous because they are associated with direct injuries and cumulative trauma disorders (CTDs). The report noted that some studies have demonstrated a 38 percent increase in CTDs as a consequence of working in deboning operations.

FSIS agrees with the statements in the report about the efficiency of AMR systems that makes meat processing operations more safe and profitable. However, for the reasons presented in this interim final rule, the Agency disagrees with the Sparks report's assertion that further rulemaking to refine the 1994 final rule is unwarranted.

Comment: A commenter asked whether FSIS agreed with the cost estimates in the Sparks Companies, Inc., report, which provided an economic analysis of the 1998 proposed AMR rule.\8\

Response: FSIS does not agree with some of the conclusions in the Sparks report. For example, FSIS believes that it is unlikely that all AMR systems will be removed and replaced with tertiary hand-deboning procedures, as the report suggests. Not all of the AMR systems are used to process split vertebral columns with exposed and extruding bone marrow tissue. Some systems are used to process only brisket or sternum and rib bones. The expected continued use of non-vertebral bones in AMR systems would considerably reduce the capital cost loss of \$40 million estimated in the report.

The report's discussion of capital costs also fails to take into account depreciation of the AMR systems since 1994, which would considerably reduce the capital cost loss. In addition, the cost of auto-knives may be somewhat over-estimated because the report assumes that the knives depreciate within a year. FSIS would suggest that the authors of the report should have used only the flow of services of the knives, not the depreciation of the entire capital stock of the knives within a year.

However, the report was helpful and provided the Agency with important data to gauge volume and yield data, for example, and to gain





a greater understanding of the extent of the AMR beef and pork industry in this country.

These comments and all of the other public comments submitted in response to the 1998 proposal are available for review in the FSIS Docket Room and at the FSIS Web site.

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#### Consumer Group Petition

Because of its concerns about the presence of spinal cord and DRG in AMR product, in 2001, a consumer group, the Center for Science in the Public Interest (CSPI) on behalf of other consumer and public health associations, petitioned USDA to institute regulatory actions to prohibit spinal cord and DRG in AMR beef products.\9\ In addition, a consortium of 14 animal welfare, farmer, environmental, and public health groups voiced similar concerns and urged USDA and the FDA to take immediate regulatory action.\10\

#### 2002 Survey of AMR Products

In order to assess the current industry practices associated with AMR systems, the petition submitted by CSPI, and the need for further Agency action with regard to AMR, the Agency determined that it needed to conduct a survey of AMR systems (i.e., the 2002 Survey of AMR Products). Another purpose of this survey was to characterize the recovered product of AMR systems regarding texture and appearance, look at current production practices (e.g., pressure settings and type of source materials) and yield data, and determine how those practices influence the calcium and iron levels of the final product.

In January 2002, FSIS began collecting random samples from the 42 piston-driven AMR systems in production at 34 establishments harvesting AMR product derived from beef vertebrae or beef vertebrae mixed with other types of beef bones. Several establishments had more than one operating AMR system processing beef vertebrae.

Over a 7-month period, samples from each AMR system that uses beef vertebrae as source material were randomly collected. An FSIS laboratory tested the products for the presence of spinal cord and DRG. At random times over the 7-month period, FSIS collected final (after the desinewer) product samples and intermediate (before the desinewer) samples from each of the active machines. In addition, the AMR system model and identification number, type of starter (input) product, and the maximum pressure applied and pressure hold or dwell time (at the maximum pressure) of the systems were noted. Most of the samples also were tested for the food chemistry constituents calcium, iron, and protein.

Although some of the establishments (4 of 34 or 12 percent) were able to produce final AMR product with no spinal cord or DRG on a consistent basis (based on all (six or more) samples being negative), other establishments consistently produced samples that tested positive for spinal cord and DRG. For the survey, approximately 35 percent of the final AMR product samples tested positive for spinal cord or DRG: 29 percent for spinal cord and 10 percent for DRG.

The occurrence of spinal cord and DRG was not considered to be significantly correlated; that is, the presence of one of these tissues in a sample did not significantly affect the likelihood of the presence of the other. This lack of significant correlation suggests that there



may be different factors that determine the presence of these tissues in AMR product. On the other hand, estimated values of excess iron and calcium were positively correlated, suggesting that there is a common set of factors that influence their levels. See the final report on the 2002 survey results in the FSIS Docket Room or at the FSIS web site for additional details.\11\

#### FSIS Directive 7160.3

In August 2003, FSIS issued Directive 7160.3, Revision 1, to provide instructions to inspection program personnel for sampling boneless comminuted beef products from AMR systems in which vertebral columns are used and on actions to take if the product contains spinal cord.\12\ The directive did not address the presence of DRG tissue in AMR product because the Agency had not included DRG in the 1998 proposed rule.

After doing follow-up verification sampling, the Agency was especially concerned that some establishments were not adequately addressing the problem of spinal cord in AMR product. The directive defined the range of follow-up actions available to the Agency when product from an AMR system is found to contain spinal cord tissue. FSIS withheld label approval for those establishments whose AMR system repeatedly failed to produce product that was free of spinal cord. Thus, these establishments effectively were not allowed to produce AMR meat from beef vertebrae.

#### Overview of This Interim Final Rule and Request for Comments

FSIS is amending the meat inspection regulations in Parts 301, 318, and 320 of the Code of Federal Regulations by modifying the definition of ``meat;'' adding or modifying non-compliance criteria for bone solids, bone marrow, brain, trigeminal ganglia, spinal cord, and DRG; requiring the development, implementation, and maintenance of a written program, including documentation and recordkeeping requirements, for ensuring process control; and declaring inedible the skulls and vertebral column bones from cattle that are 30 months of age and older. As indicated in a new Section 310.22, which is adopted in another interim final rule issued today (see Docket 03-025IF in this issue of the Federal Register), skulls and vertebral column bones from cattle 30 months of age and older are inedible and cannot be used for human food. Therefore, if skulls or vertebral column bones from cattle 30 months of age and older are used in AMR systems, the product exiting the AMR system is adulterated, and the product and the spent bone materials are inedible and cannot be used for human food. For AMR product derived from the bones of cattle younger than 30 months, the presence of CNS-type tissues will render the product misbranded. Similarly, for AMR product derived from the bones of livestock other than cattle, the presence of CNS-type tissues will result in misbranding. For AMR product derived from the bones of all livestock, the restrictions associated with bone solids and bone marrow also relate to misbranding.

FSIS is amending Sec. 301.2(b), the definition of ``meat'' to make it clear that boneless meat may not include significant portions of bone or related components, such as bone marrow, or any amount of CNS-type tissues. Therefore, product produced using an AMR system must not include significant amounts of bone or related components. It also must not include any brain, trigeminal ganglia, spinal cord, or DRG.



Section 318.24(a) provides that skulls and vertebral column bones of cattle 30 months of age and older, as provided for in a new section 310.22 which is adopted in another interim final rule issued today (See Docket 03-025IF in this issue of the Federal Register), cannot be used in AMR systems. In addition, the recovered meat product exiting the AMR system must not significantly incorporate bone solids or bone marrow, as measured by the presence of calcium and excess iron, and cannot contain any brain, trigeminal ganglia, spinal cord, or DRG.

Section 318.24(b) provides that establishments operating AMR systems are required to develop, implement, and maintain procedures that ensure that their production process is in control. The establishment must incorporate its production process procedures in a written program that is designed to ensure the ongoing effectiveness of the process control program. Because of the food safety concerns presented by SRMs, for establishments that process

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cattle, the written program must be in the establishment's Hazard Analysis and Critical Control Point (HACCP) plan, or in its Sanitation Standard Operating Procedure (Sanitation SOP) or other prerequisite program.

By declaring SRMs inedible and prohibiting their use for human food, FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained, are excluded from the human food supply.

Because BSE was recently confirmed in a cow in the United States, FSIS has determined that the SRMs, adopted in another interim final rule issued today (see Docket 03-025IF in this issue of the Federal Register), are unfit for human food. Thus, the status of these materials has changed from edible to inedible. Such a change is likely to affect the underlying hazard analysis that must be conducted as prescribed by 9 CFR 417.4(a)(3). Therefore, in response to this change, FSIS expects that establishments that slaughter cattle or process carcasses or parts of cattle will reassess their HACCP plans in accordance with 9 CFR 417.4(a)(3) to address SRMs.

Under Sec. 318.24(b), the written program must include the observation of bones entering the AMR system and the testing of the product exiting the AMR system. The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process. The establishment shall make the documentation available to inspection program personnel.

Section 318.24(b) makes clear that establishments will be expected to determine how and when they will test product for calcium, iron, spinal cord, and DRG. Based on the supporting documentation provided by the establishment, and FSIS's own verification, FSIS will make a determination whether the product is misbranded or adulterated. FSIS expects that the establishment will ensure that each production lot is in compliance with the provisions of this regulation.

Regarding the testing methodology for spinal cord and DRG, FSIS will continue to use its validated histological procedures. However, FSIS is aware that establishments have access to methodology that is not as specific or sensitive as the FSIS methodology and that is considerably less expensive to perform. FSIS encourages establishments to use any methodology that is effective. FSIS cautions establishments, however, that if the establishment's methodology is not adequate to discern complying product from non-complying product, FSIS will ensure







that non-complying product is not allowed to enter commerce.

Because of the expense and time associated with highly sensitive and specific tests, such as the methodology used by FSIS, researchers have been working on quicker and less costly tests. One such research effort has employed ELISA technology. For the 2002 AMR beef survey, an ELISA procedure was examined by FSIS, but FSIS concluded that the test was not sufficiently specific or sensitive. Not only were there many false positive and negative results (when compared to the FSIS histological results), the rates of false positive and negative results were establishment dependent. This latter finding could imply that there was some other component in the product interfering with the test.

FSIS is aware that there are a number of research efforts underway to improve the sensitivity and specificity of the rapid tests that can be used in lieu of the normative histological tests for evaluating the presence of spinal cord and DRG. FSIS does not want to preclude the use of such tests by establishments. Therefore, FSIS is soliciting information during the comment period on alternative test methods and performance specificity and sensitivity. FSIS is interested in identifying a test for use by establishments that is as sensitive to the presence of spinal cord and DRG in product as the histological test employed by FSIS, but that is less expensive and less time consuming.

The production process is not in control if the skulls of livestock entering the AMR system contain any brain or trigeminal ganglia tissue, or the vertebral column entering the AMR system has any spinal cord. In addition, the process is not in control if the recovered product contains unacceptable levels of bone solids or bone marrow, or any level of spinal cord or DRG, as provided for in Sec. 318.24(c). In addition, the production process is not in control if the product is not properly labeled or spent bone materials are not properly handled.

Section 318.24(c)(1) describes the five criteria that define when recovered AMR product may not be used and labeled as ``meat.'' They include a measure for excess bone solids (calcium content above the stated level); a measure for excess bone marrow (iron in relation to protein above the stated level); the presence of brain or trigeminal ganglia; the presence of spinal cord; and the presence of DRG.

In Sec. 318.24(c)(2), if the recovered product derived from any livestock fails under any of these criteria, it cannot be labeled as ``meat.'' In addition, product derived from beef skulls or vertebral column bones from cattle younger than 30 months containing CNS-type tissues cannot be used as an ingredient of a meat food product. For example, this product, if it contained spinal cord, cannot be labeled as ``Beef with Spinal Cord'' or ``Beef with Spinal Cord Meat Food Product'' because detached spinal cord is prohibited from use in the preparation of edible product other than for edible rendering (9 CFR 318.6(b)(4)). It also cannot be labeled as MS(Beef) because FSIS has determined MS(Beef) to be inedible and prohibited its use as human food (see Docket 03-025IF in this issue of the Federal Register). Such product can be rendered to produce products identified as beef stock, beef extract, and beef flavoring without any identification of the source materials other than ``beef'' because the source materials are edible, not inedible. FSIS has determined that it is appropriate to now prohibit product that contains CNS-type tissues derived from cattle younger than 30 months of age for use in a meat food product, except for the sale of brain or the use of brain in which its presence is required to be reflected prominently and conspicuously in labeling. FSIS has established precedent for not allowing detached spinal cord



for use in meat food products, but does allow its use for edible rendering. FSIS requests comment on whether product derived from the bones of cattle younger than 30 months (as well as product from livestock other than cattle) that may contain CNS-type tissues should continue to be allowed in edible rendering, or whether such product should be inedible and not allowed in edible rendering or allowed in descriptively labeled meat food product. FSIS requests comment on whether edible rendered products derived from bones of livestock in which the bones may contain CNS-type tissues should be required to bear a common or usual name that reflects the potential presence of CNS-tissue (e.g., ``beef stock derived from materials that may contain spinal cord''). FSIS will be working with FDA on this issue.

As discussed above, skulls or vertebral column bones from cattle 30 months of age and older may not be used at all in AMR systems. Product derived from bones of cattle other than skulls or vertebral column bones may bear a name that is not false or misleading but cannot bear the name ``Mechanically Separated (Beef).'' In another interim final rule issued today (see Docket 03-025IF in this issue of

[[Page 1883]]

the Federal Register), FSIS has determined that MS(Beef) is inedible and prohibited its use as human food. Such product would not contain CNS-type tissues because only the skulls and vertebral column bones contain CNS-type tissues.

For purposes of this rule, bone marrow from cattle is not identified as an SRM. The scientific evidence to establish that cattle bone marrow is a tissue that demonstrates infectivity is inconclusive at this time (see Docket No. 03-025IF, also published in this issue of the Federal Register for additional information about bone marrow). Therefore, product from cattle of any age (e.g., through the use of AMR systems using long bones rather than vertebral column bones) that fails to meet the bone marrow standard is misbranded. FSIS seeks comment on this issue.

Section 318.24(c)(3) provides that spent skulls and vertebral column bone materials from cattle eligible to enter an AMR system (i.e., from cattle younger than 30 months of age) are eligible for edible rendering, as is the product derived from these bones that contains CNS-type tissues (see Sec. 318.24 (c)(2)(i) or (ii)).

Although some non-complying AMR product derived from the vertebral column of pork and livestock other than cattle may be diverted to use as MS(Species), such a practice has not been customary in the past because MS(Species) rarely, if ever, is produced in the United States. FSIS is considering rulemaking on MS(Species) from species other than cattle regarding the presence of CNS-type tissue in this product and is seeking comment on this issue.

Section 320.1 is amended to extend the recordkeeping requirements to the entire AMR process control system. The current regulation applies only to the calcium criteria. This change is necessary to ensure that establishments maintain appropriate records documenting that they are controlling the entire process, including the appropriate identification and segregation of cattle and their derived products. The establishment may determine to incorporate the control procedures and recordkeeping into their HACCP plan or into their Sanitation SOP or other prerequisite program. Such control procedures may be based on the guidance prepared by the Canadian government for their industry.





#### Request for Comments

FSIS requests comments on the measures contained in this interim final rule, and specifically on whether the Agency has chosen measures that are most appropriate for preventing human exposure to the BSE agent in the United States.

#### Emergency Action

Given the fact that a cow in Washington State tested positive for BSE on December 23, 2003, it is necessary to issue this rule on an emergency basis. BSE infectivity has been confirmed in the brain, eyes, trigeminal ganglia, tonsils, spinal cord, DRG, and distal ileum. Furthermore, most of these tissues have demonstrated infectivity before experimentally infected animals developed clinical signs of disease. Thus, BSE infectivity in these tissues is not readily ascertainable. Therefore, FSIS has determined that it must take immediate action to ensure that materials that could present a significant risk to human health in beef derived from AMR systems and the spent bone materials derived from AMR systems are excluded from the human food supply.

Under these circumstances, the FSIS Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest, and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the Federal Register. FSIS will consider comments received during the comment period for this interim rule (see DATES above). After the comment period closes, the Agency will publish another document in the Federal Register. The document will include a discussion of any comments received in response to this interim rule and any amendments made as a result of those comments.

In an effort to ensure that establishments comply with this interim final rule upon publication in the Federal Register, FSIS will provide guidance to inspection program personnel regarding the implementation strategy. At a minimum, FSIS inspection program personnel will be directed to meet with management of each affected establishment to discuss how and when the establishment expects to complete its reassessment of its HACCP plan to ensure that SRMs and MS(Beef) do not adulterate product.

#### Executive Order 12866 and the Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. It has been determined to be economically significant for purposes of E.O. 12866.

The emergency situation surrounding this rulemaking makes timely compliance with Executive Order 12866 and the Regulatory Flexibility Act (5. U.S.C. 601 et seq.) impracticable.

FSIS is currently assessing the potential economic effects of this action. When this work is complete, the Agency will publish a notice of availability in the Federal Register and will provide an opportunity for public comment.

#### Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no





retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5. must be exhausted before any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

#### Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection and recordkeeping requirements included in this interim final rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0583-XXXX to the information and recordkeeping requirements.

Title: Advanced Meat Recovery Systems.

Type of collection: New.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this interim final rule in accordance with the Paperwork Reduction Act. Under this interim final rule, FSIS is requiring a new information collection activity. FSIS is requiring establishments that produce meat from AMR systems to ensure that bones used for AMR systems do not contain brain, trigeminal ganglia, or spinal cord, to test for calcium (at a different level than previously required), iron, protein, spinal cord, and DRG, to document their testing protocols, to assess the age of cattle product used in the AMR system, and to document their procedures for handling product from cattle of any age in a manner that does not cause product to be misbranded or adulterated, and to maintain records of their documentation and test results.

Estimate of burden: FSIS estimates that it will take establishments on a daily basis 30 minutes to collect the

[[Page 1884]]

information such as for calcium and iron and 30 minutes to sample for spinal cord and DRG. The Agency estimates that it will take 2 minutes to do recordkeeping of test results. FSIS also estimates that it will take establishments 2 hours to develop their testing protocols.

Respondents: Establishments that produce livestock product (e.g., beef and pork) from AMR systems.

Estimated Number of Respondents: 56.

Estimated Number of Responses per Respondent: 1,201.

Estimated Total Annual Burden on Respondents: 18,088 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, FSIS, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250-3700.

#### Additional Public Notification

Public involvement in all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this interim final rule and informed about the mechanism for providing their comments, FSIS will announce it and make copies of this Federal Register publication through the FSIS Constituent Update, which is



communicated via Listserv, a free e-mail subscription service. In addition, the update is available online through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide

information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents and stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other persons who have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information, contact the Congressional and Public Affairs Office, at (202) 720-9113. To be added to the free e-mail subscription service (Listserv) go to the ``Constituent Update'' page on the FSIS Web site at <http://www.fsis.usda.gov/oa/update.htm>. Click on the

``Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

#### Footnotes

The following sources are referred to in this document and are available for review in the FSIS Docket Room (See ADDRESSES above) between 8:30 a.m. and 4 p.m., Monday through Friday.

1. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computations Epidemiology, College of Veterinary Medicine, Tuskegee University, November 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.
2. Summary of Calendar Year 2003 AMR Testing, FSIS.
3. Hasiak, R.J. and H. Marks, The ``Advanced Meat Recovery System'' Survey Project Final Report, February 21, 1997.
4. FSIS Directive 7160.2, ``Meat'' Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems, April 14, 1997.
5. FSIS technical paper, Derivation of excess iron limits for meat products produced by Advanced Recovery Systems, July 21, 1999.
6. Wyndom, W.R. and R.A. Field, Effect of method of analysis on iron content of beef from advanced meat recovery systems, May 2000.
7. Georgetown University Center for Food & Nutritional Policy, Advanced Meat Recovery Systems, 1999.
8. Sparks Companies, Inc., Advanced Meat Recovery Systems--An Economic Analysis of Proposed USDA Regulations, July 1999.
9. Letter to FDA and USDA, submitted by Public Citizen, and signed by the Animal Welfare Institute, Cancer Prevention Coalition, Center for Food Safety, Community Nutrition Institute, Family Farm Defenders, Farm Sanctuary, Global Resource Action Center for the Environment, Government Accountability Project, Project Humane Farming Association, Institute for Agriculture and Trade Policy, National Family Farm Coalition, Organic Consumers Association, Public Citizen, and the U.S. Public Interest Research Group, April 13, 2001.
10. Petition for Regulatory Action to Bar the Use of Spinal Cord and Columns and Other Potentially Infectious Tissue from Beef in the Human Food Supply, submitted by the Center for Science in the Public



Interest, on behalf of the American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, and Safe Tables Our Priority, August 9, 2001.

11. Analysis of 2002 FSIS Bovine AMR Survey Results, prepared by the USDA, FSIS, February 2003.

12. FSIS Directive 7160.3, Revision 1, Advanced Meat Recovery Using Beef Vertebral Raw Materials, August 25, 2003.

#### List of Subjects

##### 9 CFR Part 301

Meat and meat products.

##### 9 CFR Part 318

Meat inspection, Records.

##### 9 CFR Part 320

Meat inspection, Records.

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For the reasons set forth above, FSIS is amending 9 CFR, chapter III, as follows:

#### PART 301--TERMINOLOGY

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1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

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2. In Sec. 301.2, the definition of ``Meat'' is revised to read as follows:

#### Sec. 301.2 Definitions.

\* \* \* \* \*

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).





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PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND  
PREPARATION OF PRODUCTS

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3. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901-1906; 21 U.S.C. 601-695; 7  
CFR 2.7, 2.18, and 2.53.

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4. Section 318.24 is revised to read as follows:

Sec. 318.24 Product prepared using advanced meat/bone separation  
machinery; process control.

(a) General. Meat, as defined in Sec. 301.2 of this subchapter,  
may be derived by mechanically separating skeletal muscle tissue from  
the bones of livestock, other than skulls or vertebral column bones of  
cattle 30 months of age and older as provided in Sec. 310.22 of this  
subchapter, using advances in mechanical meat/bone separation machinery  
(i.e., AMR systems) that, in accordance with this section, recover  
meat--

(1) Without significant incorporation of bone solids or bone marrow  
as measured by the presence of calcium and iron in excess of the  
requirements in this section, and

(2) Without the presence of any brain, trigeminal ganglia, spinal  
cord, or dorsal root ganglia (DRG).

[[Page 1885]]

(b) Process control. As a prerequisite to labeling or using product  
as meat derived by the mechanical separation of skeletal muscle tissue  
from livestock bones, the operator of an establishment must develop,  
implement, and maintain procedures that ensure that the establishment's  
production process is in control.

(1) The production process is not in control if the skulls entering  
the AMR system contain any brain or trigeminal ganglia tissue, if the  
vertebral column bones entering the AMR system contain any spinal cord,  
if the recovered product fails otherwise under any provision of  
paragraph (c)(1), if the product is not properly labeled under the  
provisions of paragraph (c)(2), or if the spent bone materials are not  
properly handled under the provisions of paragraph (c)(3) of this  
section.

(2) The establishment must document its production process controls  
in writing. The program must be designed to ensure the on-going  
effectiveness of the process controls. If the establishment processes  
cattle, the program must be in its HACCP plan, its Sanitation SOP, or  
other prerequisite program. The program shall describe the on-going  
verification activities that will be performed, including the  
observation of the bones entering the AMR system for brain, trigeminal  
ganglia, and spinal cord; the testing of the product exiting the AMR  
system for bone solids, bone marrow, spinal cord, and DRG as prescribed  
in paragraph (c)(1) of this section; the use of the product and spent



bone materials exiting the AMR system; and the frequency with which these activities will be performed.

(3) The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process.

(4) The establishment shall make available to inspection program personnel the documentation described in paragraphs (b)(2) and (b)(3) of this section and any other data generated using these procedures.

(c) Noncomplying product. (1) Notwithstanding any other provision of this section, product that is recovered using advanced meat/bone separation machinery is not meat under any one or more of the following circumstances:

(i) Bone solids. The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 130.0 mg per 100 g.

(ii) Bone marrow. The product's added iron content, measured by duplicate analyses on individual samples and rounded to the nearest 10th, is more than 3.5 mg per 100 g.\1\

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\1\ The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100 g measured and rounded to the nearest 100th or more for that sample, minus the product of three factors: (1) The iron to protein ratio (IPR) factor associated with corresponding hand-deboned product; (2) the obtained protein (P) result (%) for that sample; and (3) a constant factor of 1.10. In formula, this can be written as:  $ExcFe = mFe - IPR \times Protein \times 1.10$ , where ExcFe represents the excess iron, expressed in units of mg/100 g; mFe represents the measured level of iron (Fe, mg/100 g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and ``Protein'' is the measured level of protein rounded to the nearest 100th and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.

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(iii) Brain or trigeminal ganglia. Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.

(iv) Spinal cord. Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.

(v) DRG. The product that exits the AMR system contains DRG.

(2) If product that may not be labeled or used as ``meat'' under this section meets the requirements of Sec. 319.5 of this subchapter, it may bear the name ``Mechanically Separated (Species)'' except as follows:



(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR system shall not be used as an ingredient of a meat food product.

(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.

(iii) If product derived from any bones of cattle of any age does not comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name ``Mechanically Separated (Beef).''

(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.

#### PART 320--RECORDS, REGISTRATION AND REPORTING

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5. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, and 2.53.

#### Sec. 320.1 [Amended]

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6. Section 320.1, paragraph (b)(10), is amended by removing ``of calcium content in meat derived from'' and adding, in its place, ``documenting the development, implementation, and maintenance of procedures for the control of the production process using.''

Done in Washington, DC, on: January 7, 2004.

Garry L. McKee,

Administrator.

[FR Doc. 04-626 Filed 1-8-04; 1:43 pm]









# Air-Injection Stunning



## Teaching Workshop

Bovine Spongiform Encephalopathy (BSE)

Air-injection Stunning



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### Air-injection Stunning Prohibited

- January 12, 2004

- FSIS published an interim final rule with request for comments. (69 Fr 1885, January 12, 2004)
- Amends FSIS regulations to prohibit air-injection stunning of cattle.

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### Air-injection Stunning

- "Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle." (313.15 (b) (2) (ii))

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## Harvard Study

- Harvard Center for Risk Analysis conducted a risk assessment for BSE:
  - FSIS commissioned the study and released the results on November 30, 2001.
  - Among other things, the risk assessment compared standard captive bolt stunning and captive bolt stunning with air-injection.
  - Found that air-injection stunners can fail on occasion and result in an increase of CNS tissue disseminated into the circulatory system of cattle, thereby increasing the probability of BSE agent transfer.

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## Air-injection Stunning and BSE

- Other studies have shown that:
  - Air-injection stunning can force visible pieces of brain and other Central Nervous System (CNS) tissue—known as macro-emboli—into the circulatory system and organs of stunned cattle.
  - Most of the infectivity in cattle that have BSE is found in the CNS tissue (brain and spinal cord).

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## European Commission Opinion

- In early 2002, the European Commission's Scientific Steering Committee concluded that air-injection stunning was the method which had the highest risk of disseminating CNS tissues to other tissues and organs.

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### Air-Injection Stunning

- Changes in regulations:
  - Previous regulation 9 CFR 310.13 specifically listed air-injection captive bolt stunning as an approved method.
    - Amended to prohibit its use in cattle.
  - Regulation 313.15 (b) (2) (ii)
    - New paragraph added to prohibit air-injection stunners.

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### Stunning Devices Used in the U.S.

- Two types of captive bolt stunners:
  - Penetrative
  - Non-penetrative
- Most cattle slaughter plants in U.S. use penetrative captive bolt stun guns (without air-injection).
- FSIS does know that very few, if any, plants in the U.S. use air-injection stunning.

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### Stunning Methods

- FSIS inspection personnel verify that slaughter plants are using approved stunning devices.

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## Imported Beef

- Imported products must meet all safety standards for products produced in the U.S.
- Therefore, foreign establishments that use air-injection stunning for cattle are prohibited from importing beef products into the U.S.

## The Future

- There are relatively few studies on stunning techniques and CNS tissue.
- If further studies indicate that other stunning techniques introduce CNS tissues into the circulatory system of cattle, FSIS will consider prohibiting their use as well.

## Food Safety and Inspection Service (FSIS) Prohibitions On Air-injection Stunning Devices

Because BSE was confirmed in a cow in the United States on December 25, 2003, FSIS is prohibiting the use of penetrating stunning devices that inject air into the cranial cavity of cattle. This requirement is to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughtering process. In emergency rulemaking, FSIS is prohibiting the use of certain parts of cattle carcasses in food.

Previous Requirements Before January 12, 2004	Current Requirements Beginning January 12, 2004
<b>Situation:</b> <ul style="list-style-type: none"> <li>No BSE positives had been found in the U.S.</li> </ul>	<b>Situation:</b> <ul style="list-style-type: none"> <li>The first BSE positive for a cow in the U.S. was confirmed on December 25, 2003.</li> </ul>
<b>Materials prohibited from use in food:</b> <ul style="list-style-type: none"> <li>Tonsils and distal ileum,</li> <li>Detached spinal cords could not be used in edible products, but could be used in edible rendering.</li> </ul>	<b>Materials prohibited from use in food:</b> In all cattle, "specified risk materials" (SRMs) are: <ul style="list-style-type: none"> <li>Distal ileum of the small intestine (but to ensure complete removal, FSIS requires entire small intestine to be removed)</li> <li>Tonsils</li> </ul> In cattle 30 months of age or older, additional "specified risk materials" (SRMs) are prohibited from use in human food. They are: <ul style="list-style-type: none"> <li>Brain</li> <li>Skull</li> <li>Eyes</li> <li>Trigeminal ganglia</li> <li>Spinal cord</li> <li>Vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum)</li> </ul> Dorsal root ganglia (DRG). (Interim final rule and request for comments was published January 12, 2004.)
<b>Air-injection stunning devices:</b> Allowed.	<b>Air-injection stunning devices:</b> <u>Not</u> allowed. (Interim final rule and request for comments was published January 12, 2004.)

<b>Number of plants in the U.S. using air-injection stunning devices:</b> FSIS was not aware of any.	
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## Regulatory Changes

NOTE: The interim final rule which includes the preamble and these changes follows this section.

### Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter

#### List of Subjects

##### 9 CFR Part 310

Animal diseases, Meat inspection.

##### 9 CFR Part 313

Animal welfare, Livestock, Meat inspection.

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For the reasons discussed in the preamble, FSIS amends 9 CFR chapter III as follows:

#### PART 310--POST-MORTEM INSPECTION

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1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

#### Sec. 310.13 [Amended]

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2. Section 310.13 is amended as follows: Paragraph (a)(2)(iv)(C) is amended by adding the phrase ``of all livestock except cattle'' after ``into the skull'' and before ``in conjunction with''.

#### PART 313--HUMANE SLAUGHTER OF LIVESTOCK

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1. The authority citation for part 313 continues to read as follows:

Authority: 7 U.S.C. 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

#### Sec. 313.15 [Amended]

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2. Section 313.15 is amended as follows:

Paragraph (b)(2) is amended by revising the paragraph heading, designating the text as paragraph (b)(2)(i), and by adding a new paragraph (b)(2)(ii). The added and revised text reads as follows:





Sec. 313.15 Mechanical; captive bolt.

\* \* \* \* \*

(b) \* \* \*

(2) Special requirements and prohibitions.

\* \* \* \* \*

(ii) Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle.



[Federal Register: January 12, 2004 (Volume 69, Number 7)]

[Rules and Regulations]

[Page 1885-1891]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310 and 313

[Docket No. 01-033IF]

Prohibition of the Use of Certain Stunning Devices Used to  
Immobilize Cattle During Slaughter

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule with request for comments.  
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SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to prohibit the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle. This rulemaking responds to the findings of a risk assessment on bovine spongiform encephalopathy (BSE) conducted by the Harvard Center for Risk Analysis (referred to as the Harvard study) and is part of a series of actions that the USDA is taking to strengthen its BSE prevention programs.

The Harvard study found that, owing to already ongoing Federal programs, the U.S. is highly resistant to the introduction and spread of the disease. Even so, the USDA response to BSE has always been proactive and preventive.

Therefore, FSIS is taking this action to address the potential risk posed by stunning devices that may force visible pieces of brain, known as macro-emboli, into the circulatory system of stunned cattle.

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DATES: Effective January 12, 2004; comments received on or before April 12, 2004 will be considered prior to issuance of a final rule.

ADDRESSES: Send an original and two copies of comments to: FSIS Docket Clerk, Docket 01-033IF, Room 102, Cotton Annex, 300 C Street, SW., Washington, DC 20250-3700. Reference materials cited in this document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and



Program Development, Food Safety and Inspection Service, U.S.  
Department of Agriculture, Washington, DC 20250-3700; (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

BSE is a slowly progressing, fatal degenerative disease that affects the central nervous system (CNS) of cattle. BSE belongs to the family of diseases known as the transmissible spongiform encephalopathies (TSEs), which include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob Disease (CJD) in humans. In 1996, following outbreaks of BSE in cattle in the United Kingdom, scientists found a possible link between BSE and a new variant of CJD, commonly referred to as variant CJD (vCJD). While it is not certain how BSE may be spread to humans, evidence indicates that humans may acquire vCJD by consuming parts of cattle that contain the BSE agent.

The U.S. government has taken a number of actions to prevent the spread of BSE into the U.S. Since 1989, the USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and certain animal products from cattle, including rendered protein products, from the United Kingdom and certain other countries where BSE is known to exist. In 1997, because of concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. As of December 7, 2000, APHIS has prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concerns that feed intended for cattle may have been cross-contaminated with the BSE agent.

APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the U.S. and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the U.S. BSE was, in fact, identified in a cow in Washington State on December 23, 2003; as a result, the plan was immediately put into effect. Other Federal agencies also have contingency plans that work in concert with the USDA plan. In 1997, the Food and Drug Administration (FDA) issued a final rule prohibiting the use of most mammalian protein in animal feeds for cattle and other ruminants. Under the FDA's rule, animal feed manufacturers must keep records sufficient to track any material that contains prohibited protein (prohibited material) throughout its receipt, processing, and distribution, must have processes in place to prevent co-mingling between ruminant feed and non-ruminant feed containing prohibited materials, and must ensure that non-ruminant feed containing prohibited materials is labeled conspicuously with the statement ``Do not feed to cattle and other ruminants.'' These regulations are intended to prevent the spread of BSE in U.S. cattle through feed contaminated with the BSE agent. In addition, the Centers for Disease Control and Prevention (CDC) leads a surveillance program for vCJD in the U.S.

On November 30, 2001, the USDA released the results of a risk assessment on BSE conducted by the Harvard Center for Risk Analysis that evaluates the ways BSE could spread in the U.S. (Ref. 1, available for viewing by the public in the FSIS Docket room and on the Internet at <http://www.fsis.usda.gov/OA/topics/bse.htm>). The Harvard study also





provides government agencies with a science-based approach to evaluate measures already in place to prevent the spread of BSE into the U.S. and to identify additional actions that should be taken to minimize the risk of BSE. The Harvard study shows that early prevention systems put into place by the USDA and the Department of Health and Human Services (HHS) would prevent BSE from spreading throughout the country.

Although the Harvard study found that the U.S. was highly resistant to the spread of BSE, as previously mentioned, the USDA response to BSE has always been proactive and preventive. Therefore, in response to the Harvard study, on November 30, 2001, the Secretary of Agriculture announced a series of actions that the Department would take to strengthen its BSE prevention programs and to maintain the government's vigilance against the spread of BSE. One of these actions was to issue a proposed rule to prohibit the use of certain stunning devices used to immobilize cattle during slaughter. This action was identified because certain methods used to stun cattle (i.e., render them unconscious before they are slaughtered) have been found to force visible pieces of CNS tissue, known as macro-emboli, into the circulatory system of stunned cattle. Most of the infectivity in cattle that have BSE is found in the CNS tissue, i.e., brain and spinal cord.

#### Stunning and the Humane Methods of Slaughter Act

Section 3(b) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 603(b)) requires that any cattle or other livestock species slaughtered or handled in connection with slaughter under Federal inspection be handled in accordance with the provisions of the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. 1901-1906). The HMSA states that ``\* \* \* it is \* \* \* the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods'' (7 U.S.C. 1901). The HMSA requires that livestock be rendered insensible to pain before being shackled, hoisted, thrown, cast, or cut (unless they are slaughtered and handled in connection with slaughter in accordance with certain specified religious ritual requirements) (7 U.S.C. 1902, 1906). The HMSA also authorizes the Secretary of Agriculture (and FSIS by delegation) to designate methods of slaughter and handling in connection with slaughter that conform to the policy of the HMSA (7 U.S.C. 1904(b)).

Pursuant to the authority granted under the HMSA, FSIS promulgated regulations that prescribe requirements for the humane treatment of livestock. These regulations, which are codified at 9 CFR part 313, identify, among other things, humane methods of stunning for specified livestock species (see 9 CFR 313.5, 9 CFR 313.15, 9 CFR 313.30). 9 CFR 313.15 sets forth the requirements for the use of captive bolt stunning for livestock. There are two types of captive bolt stunners, penetrative and non-penetrative. Both are permitted to be used to stun cattle prior to bleeding. In addition, the FSIS post-mortem inspection regulations, at 9 CFR 310.13, specifically list air-injection captive bolt stunning as an approved method for injecting air into the carcasses or parts of carcasses of livestock (9 CFR 310.13(a)(2)(iv)(C)).

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Most slaughter establishments use penetrative captive bolt stun guns to render cattle unconscious, quickly and painlessly prior to



slaughter. Penetrative captive bolt stun guns have steel bolts, powered by either compressed air or a blank cartridge. The bolt is driven into the animal's brain. In the past, captive bolt stun guns were often built or modified to inject compressed air into the cranium of cattle, so as to disrupt the brain structures and induce total and prolonged unconsciousness, to ensure that cattle were slaughtered in a humane manner. Studies have shown that penetrative captive bolt stunners that incorporate air-injection can force visible pieces of brain and other CNS tissue into the circulatory system of stunned cattle. These studies are discussed in greater detail below.

The regulations in 9 CFR 313.15 do not distinguish among the different types of penetrative captive bolt stunners, such as those that inject air into the cranium of the animal and those that do not. Both methods of stunning are considered to be humane, and both are permitted to be used on cattle. Thus, under the regulations, captive bolt stunners that do not inject air can be used to slaughter cattle humanely.

#### Summary of Studies on Stunning Methods

The frequency with which CNS tissue enters the circulatory system of stunned cattle and the size of the CNS tissue emboli depend on the method of stunning used. Fragments of CNS tissue that can be detected visually are referred to as CNS macro-emboli, while pieces of CNS tissue that can only be detected microscopically or with the use of CNS tissue markers are referred to as micro-emboli. Studies have found that when air-injection pneumatic stunners are used, CNS tissue emboli can be identified visually in the pulmonary artery and in the right ventricle of the heart and microscopically in the jugular venous blood (Refs. 2-4, available for viewing by the public in the FSIS Docket Room). Air-injection pneumatic stunning has also been found to result in a high incidence of visually observed blood clots in the right ventricle of the heart (Ref. 3, available for viewing by the public in the FSIS Docket Room).

Other types of penetrative captive bolt stunners besides those that use air injection include pneumatically operated stunners that do not inject air and standard cartridge-fired captive bolt stunners. One study found that both pneumatically operated stunners that do not inject air and cartridge fired captive bolt stunners resulted in visually detectable blood clots in the right ventricle of the heart, although only a small number of blood clots were observed when a cartridge fired captive bolt was used (Ref. 3, available for viewing by the public in the FSIS Docket Room). The observation of visible blood clots cannot be used as direct evidence of the presence of CNS tissue; however, the presence of visible blood clots does indicate some type of interference with blood flow through the heart. The blood clots observed in the study were not analyzed for the presence of CNS tissue. More studies are needed to determine whether, and if so, the degree to which, CNS tissue may be present in blood clots observed in the heart of stunned cattle.

In general, studies have not demonstrated that penetrative captive bolt stunning without air injection results in CNS tissue macro-emboli in the blood or other tissues of stunned cattle. One study detected no visible or microscopic fragments of brain tissue in jugular venous blood of cattle when a penetrative captive bolt without air injection was used (Ref. 4, available for viewing by the public in the FSIS Docket Room). This same study found no evidence of CNS tissue in





jugular venous blood using assays for CNS markers. Another study did not detect CNS tissue in the lungs of cattle by gross examination or by histopathology of selected areas of the lung when captive bolt stunning without air-injection was used (Ref. 5, available for viewing by the public in the FSIS docket room). However, there is one study in which the presence of CNS tissue markers was weakly detected by assay of emboli found in the lungs after cattle were stunned using a penetrative captive bolt without air injection (Ref. 6, available for viewing by the public in the FSIS docket room). The authors of this study concluded that the results suggest that the contamination of the lung with CNS tissue after using a conventional cartridge-fired captive bolt stunner can not be excluded; however, the incidence appears to be very low. The authors also concluded that the presumed CNS tissue emboli, if present at all, are microscopically small.

Although not documented in the published studies, in addition to the heart and lungs, FSIS inspection program personnel have reported observing CNS tissue macro-emboli in the liver and kidney of cattle stunned with pneumatic powered air-injection stunners. The Agency has photographs and histopathology reports documenting the presence of CNS tissue macro-emboli when hearts, lungs, livers, and kidneys from cattle stunned using air-injection devices are dissected.\1\

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\1\ These are available for viewing by the public in the FSIS docket room.

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## Risk Considerations

### 1. European Scientific Steering Committee Opinion

The European Commission's (EC) Scientific Steering Committee (SSC) adopted an opinion on Stunning Methods and BSE Risks at its January 10-11, 2002, meeting that, among other things, describes the tissues and organs that are at risk of being contaminated with CNS material when certain stunning methods are used on certain ruminants (Ref. 7, available for viewing by the public in the FSIS Docket Room). In the opinion, the SSC ranks these stunning methods according to the risk and possible level of CNS tissue contamination. The opinion was based on a scientific report prepared by the EC's TSE/BSE ad hoc Group (Ref. 8, available for viewing by the public in the FSIS Docket Room). The stunning methods addressed in the SSC report include: pneumatic stunner that injects air, pneumatic stunner that does not inject air, captive bolt stunner with pithing, captive bolt stunner without pithing, non-penetrative stunner, and electro-narcosis. Pithing is the insertion of an elongated rod-shaped instrument into the cranial cavity of a stunned animal to further lacerate the CNS tissue. This stunning method is banned by the E.U. and has never been used in the U.S.

The SSC concluded that if brain damage occurs during any type of penetrative stunning, and CNS particles are disseminated into the blood, the tissues and organs likely to be contaminated with CNS tissue are, in decreasing order of risk, the blood, pulmonary arteries and lung, and right atrium and ventricles of the heart. The SSC also concluded that the risk of CNS tissue contamination of any other tissue as a result of penetrative stunning was absent or negligible. However, in its report, the EC's TSE/BSE ad hoc committee noted that little data is available to determine whether CNS tissue emboli can occur in a





homogenized form or just as structured tissue fragments.

As stated in the report, it could be that homogenized CNS tissue may be able to enter arterial circulation and spread to other tissues, including spleen and muscle. There is one study in which marker bacteria placed on a captive bolt pistol was recovered from the spleen, and marker bacteria placed on a pithing rod was found in both

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spleen and muscle (Ref. 9, available for viewing by the public in the FSIS Docket Room).

In its opinion on stunning methods, the SSC ranked the various stunning methods used at slaughter in the E.U. according to the risk for contamination of other tissues with CNS tissue and the possible level of contamination. Of the stunning methods evaluated, the SSC concluded that pneumatic stunners that inject air present the highest risk of brain damage and dissemination of CNS tissue to other tissues and organs, followed by pneumatic stunning without air injection, captive bolt stunning with pithing, and captive bolt stunning without pithing. The SSC found that non-penetrative stunning methods and electro-narcosis present a negligible risk of causing CNS tissue emboli.

According to the TSE/BSE ad hoc committee report, there is no accurate estimate of the size range of CNS emboli that occurs as a result of certain stunning methods or of the level of the BSE agent in the CNS tissues of animals incubating the disease. However, the report does state that `` \* \* \* it is clearly evident that if visible CNS material is found \* \* \* it is clear that if this tissue was TSE-infected the organ in which it resides presents a TSE risk.'' Thus, based on the conclusions of the TSE/BSE ad hoc committee, FSIS has determined that methods of stunning that cause contamination of tissues and organs with visible CNS tissue macro-emboli are the methods most likely to present a risk of exposing humans to the agent that causes BSE if used on an animal that has BSE.

The SSC noted that any risk to consumers from contamination of tissues and organs with CNS tissue depends on the level of BSE infectivity in the brain of the stunned animal. Thus, the importance of the stunning methods used becomes irrelevant if cattle brains can be assumed to be free of the BSE agent, which, according to the SSC, would be the case for all cattle under one year of age regardless of the country or origin. Furthermore, the SSC determined that when applied to cattle below 30 months of age from any country, stunning methods other than stunning with a pneumatic gun that injects air under pressure, or any stunning methods accompanied by pithing, are likely to result in a much lower or no significant risk of contamination with the BSE agent.

## 2. The Harvard Risk Assessment's Evaluation of Stunning Methods

The Harvard risk assessment model has two stunning methods built in, standard captive bolt stunning and captive bolt stunning with air-injection (Ref. 1, available for viewing by the public in the FSIS docket room and on the Internet at <http://www.fsis.usda.gov/OA/topics/bse.h>). The Harvard study does not differentiate between pneumatic

powered captive bolt stunners without air-injection and cartridge fired captive bolt stunners without air-injection. In the risk assessment, Harvard estimates the probability that each method will result in CNS



tissue emboli contamination of certain bovine tissues and organs, and the degree to which contamination might occur. In its model, Harvard assumes that if a stunning method results in CNS tissue emboli, the blood, heart, lungs, and liver may be contaminated.

Harvard estimates that for each BSE-infected animal stunned with a standard captive bolt stunner (without air injection) there is a 50 percent probability that a very small fraction of the BSE agent will be transferred to the blood. This small fraction of the BSE agent is what would be contained within micro-emboli that might occur. Harvard also estimates that for each BSE-infected animal stunned with a captive bolt stunner that uses air-injection, there is a 31 percent, 16 percent, 3 percent, and 0.6 percent probability that a fraction of the BSE agent will transfer to the blood, heart, lung, and liver, respectively. The probability and amount of the BSE agent transferred varies, with the greatest fraction in the blood, a lower fraction in the heart and lungs, and the lowest in the liver.

Harvard found that stunners that use air-injection have a potential to fail on occasion, which results in an increase in CNS tissue emboli formation. Thus, in its risk assessment model, Harvard estimates that when a BSE infected animal is stunned with a malfunctioning captive bolt stunner that uses air-injection, the probability of BSE agent transfer occurring can be approximately 10 times higher for the lung and liver, twice as high for the heart, and 50 percent higher for the blood. Harvard estimated that the amount of BSE agent transferred to these tissues would be approximately ten times higher than the amount transferred with a working air-injection stunner.

When evaluating the potential impact that stunning methods may have on the introduction and spread of BSE in the U.S., for its ``base case'' scenario Harvard assumes that air-injection stunning is not used in the U.S., and for its ``worst case'' scenario Harvard assumes that air-injection stunning is used 15 percent of the time. The base case is based upon the present state of the U.S. cattle population, and the existing government regulations and prevailing agricultural practices. When the base case scenario is compared with the worst case scenario, and it is assumed that ten BSE-infected cattle have been introduced into the U.S. system, the number of cattle ID50s that would be potentially available for human exposure increases from 35 to 41 or approximately 17 percent. A cattle oral ID50 is the amount of BSE infectious tissue that would on average cause 50 percent of cattle exposed to develop BSE. Although the Harvard study found that the stunning method used is not a major potential source of human exposure to cattle ID50s, it still found that the number of cattle ID50s available for human exposure would increase with greater use of air-injection stunning.

#### Prohibition of Air-Injection Stunning

When developing this rule, FSIS reviewed the published studies on stunning methods and CNS tissue emboli to determine which stunning methods that have been used on cattle in the U.S. are likely to result in CNS tissue macro-emboli. The collective findings of the studies indicate that the only stunning technique that has been used in the U.S. that conclusively results in CNS tissue macro-emboli when used to stun cattle is pneumatic-powered captive bolt stunning with air injection. Furthermore, the findings of the Harvard study on BSE and the SSC Opinion on Stunning Methods and BSE Risks, indicate that, of all the stunning devices used on cattle in the U.S., pneumatic-powered



captive bolt stunners that inject air present the highest risk of exposing humans to the BSE agent.

Prohibiting the use of air-injection stunning for cattle in the U.S. is consistent with many international stunning requirements for cattle. For example, the E.U. prohibits the use of air-injection stunning for cattle for its member countries.\2\ The E.U. also prohibits the importation of meat products from cattle from the U.S., as well as many other countries, that have been stunned using air-injection.\3\ Canada also prohibits the use of air-injection stunning for cattle.\4\ Thus,

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prohibiting the use of air-injection stunning for cattle in the U.S. would help to ensure that U.S. establishments that export beef products to foreign countries are not using air injection stunning, which could promote trade with certain countries.

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\2\ Council Directive 93/119/EC, 22 December, 1993 (Official Journal L 340, 31/12/1993., p. 21).

\3\ Commission Regulation (EC) No. 999/2001, 22 May 2001, as amended by Regulation (EC) No. 270/2002 14 February 2002 (Official Journal L. 045, 15/02/2002. p. 13-14).

\4\ Meat Hygiene Directive 2002-21, April 8, 2002.

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Meat products exported from another country to the U.S. must meet all safety standards applied to meat food products produced in the U.S. Once this rule is in effect, foreign establishments that use air-injection stunning for cattle would be prohibited from importing beef products into the U.S. Thus, prohibiting the use of air-injection stunning in the U.S. would also address the potential risk associated with imported beef products produced from cattle stunned using air-injection.

As noted in the E.U. SSC report on Stunning Methods and BSE Risks, there are relatively few studies on stunning techniques and CNS tissue emboli, and the methods used in the studies that have been done are inconsistent. Thus, if further studies indicate that stunning techniques used in the U.S. other than air-injection stunning result in CNS tissue macro-emboli, the Agency will consider prohibiting the use of other stunning techniques as well.

FSIS' authority to prohibit the use of captive bolt stunning devices that inject air into the cranium of cattle derives from the FMIA (21 U.S.C. 601(m), 621). When air-injection stunners cause CNS tissue to become dislodged from the brains of cattle, the circulatory systems of the stunned cattle become contaminated with visible CNS macro-emboli. As noted in the E.U. SSC report and the Harvard study, this condition could promote the spread of the BSE agent in the carcass if the animal were infected with BSE because CNS tissue macro-emboli that contain the BSE agent could become lodged in other, edible tissues or organs. FSIS believes that it should not wait until BSE is detected in this country before putting in place appropriate prophylactic measures. By prohibiting the use of air-injection stunning for cattle, FSIS seeks to eliminate a foreseeable source of risk. This action is necessary to strengthen the U.S. Government's BSE prevention efforts.







## Emergency Action

Given the fact that a cow in Washington State tested as positive for BSE on December 23, 2003, it is necessary to issue this rule on an emergency basis. BSE infectivity has been confirmed in the brain, eyes, trigeminal ganglia, tonsils, spinal cord, dorsal root ganglia, and distal ileum. Furthermore, most of these tissues have demonstrated infectivity before experimentally infected animals developed clinical signs of disease. Thus, BSE infectivity in these tissues is not readily ascertainable. Therefore, FSIS has determined that it must take immediate action to ensure that materials that could present a significant risk to human health in beef, as a consequence of stunning practices, are prohibited.

Under these circumstances, the FSIS Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest, and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the Federal Register. FSIS will consider comments received during the comment period for this interim rule (see DATES above). After the comment period closes, the Agency will publish another document in the Federal Register. The document will include a discussion of any comments received in response to this interim rule and any amendments made as a result of those comments.

## Executive Order 12866 and Regulatory Flexibility Act

This interim final rule has been determined to be significant as defined in Executive Order 12866, and therefore, it has been reviewed by the Office of Management and Budget.

FSIS is not aware of any cattle slaughter establishments that use air-injection stunning. Therefore, there appear to be no immediate quantifiable costs or benefits associated with this action. However, since research has shown that the practice poses a risk of exposing humans to materials that could contain the BSE agent, and because the technology was used in the U.S. as recently as the 1990's, FSIS believes that this prohibition is a necessary action to help strengthen the U.S. Government's BSE prevention programs.

FSIS has conducted two separate surveys on the use of air injection stunning in official U.S. cattle slaughter establishments. The first survey was conducted from late 1999 to early 2000 and was limited to 72 cattle slaughter establishments located in two FSIS Districts. The second survey was conducted from May 2002 to October, 2002 and involved 270 establishments that slaughter cattle nationwide. Neither of these surveys detected the use of air-injection stunning devices on cattle in official U.S. cattle slaughter establishments. In addition, in July 2002, the seventeen veterinarians in charge of verifying humane slaughter practices in U.S. slaughter plants reported to FSIS headquarters that they knew of no beef slaughter establishments that use air-injection stunning.

Under section 301 of the FMIA, States are permitted to operate their own meat inspection programs provided that State requirements are at least equal to those imposed by the Federal government (21 U.S.C. 661). Meat products produced under State inspection may only be sold within the State. Thus, when it becomes effective, this rule could impact state-inspected establishments that still use air-injection stunning on cattle. However, FSIS is not aware of any state-inspected plants that use this method of stunning. In November 2002, FSIS



conducted an informal survey of State officials on the use of air-injection stunners in state-inspected cattle slaughter establishments. The survey detected no state-inspected establishments that were using air-injection stunning on cattle.

FSIS is aware of only two companies that have sold air-injection stunning equipment to cattle slaughter establishments in the U.S. One of these companies informed the Agency that it no longer manufactures air-injection stunners, and that in the U.S. it had replaced existing stunners with ones that do not use air injection, at its own cost in the late 1990's. The other manufacturer told FSIS that, although it still produces air-injection stunners, it does not sell any in the U.S. and is in the process of phasing out production of these devices.

The E.U. and Canada ban air-injection stunning of cattle and prohibit the importation of beef made from cattle stunned in this manner. Thus, U.S. cattle slaughter establishments that export beef products to these countries already can not use air-injection stunners on those cattle whose products are intended for export.

Meat products exported from another country to the U.S. must meet all safety standards applied to food produced in the U.S. Thus, any foreign establishments that export meat products to the U.S. that use air-injection stunning on cattle may incur costs to replace or modify air-injection stunners or be prohibited from exporting beef products to the U.S. In 2000, approximately 87 percent of the beef and veal imported into the U.S. (fresh and frozen) came from Australia, New Zealand, and Canada; approximately 10 percent from Argentina, Brazil, and Uruguay; and approximately 3 percent from Costa Rica, Honduras, Mexico, and Nicaragua (Ref 10, available for viewing by the public in the FSIS Docket Room).

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As previously mentioned, Canada already prohibits the use of air injection stunners on cattle. Therefore, this rule would have no impact on Canadian establishments that export beef to the U.S. Although Australian law does not ban the use of air-injection stunning, to be used in Australia, any new stunning system must be approved by the Australian Quarantine and Inspection Service (AQIS). There have been trials of low pressure air injection stunning in Australia. However, AQIS has not approved any of these devices for general use. Furthermore, an AQIS official informed FSIS that there is a high degree of awareness among both the regulators and the industry in Australia about the potential problems with this type of stunning. It is unlikely that its introduction in Australia will be sought. New Zealand food safety laws do not allow for the use of air-injection stunning.

Both stunning manufacturers that have reported selling air-injection stunning equipment in the U.S. in the past, also have reported that they have sold air-injection stunning equipment to cattle slaughter establishments in South America, and one of them still sells air-injection stunning equipment to cattle slaughter establishments in Mexico, South America, and Eastern Europe. However, FSIS international auditors have not detected the use of air-injection stunners during audits of cattle slaughter establishments in Mexico and South America over the past three years, and the U.S. imports very little, if any, beef products from Eastern Europe. The Agency is continuing to gather data on the international use of air-injection stunning.

For those establishments, if any, that are using air-injection





stunning, based on conversations with stunning equipment manufacturers, FSIS estimates that the cost of modifying or replacing an individual piece of equipment could range from \$1,500.00 to \$2,000.00.

#### Regulatory Flexibility Act

The Administrator, FSIS, has determined that this rule will not have a significant economic impact, as defined by the Regulatory Flexibility Act (5 U.S.C. 601), on a substantial number of small entities.

As discussed above, FSIS is not aware of any cattle slaughter establishments that use air-injection stunning, regardless of the size of the establishment. Thus, it is likely that this rule will have no economic impact on entities of any size. Any small firms that are using air-injection stunning on cattle would incur costs to replace or modify the equipment, which, as stated above, are estimated to range from \$1,500.00 to \$2,000.00 per piece of equipment.

#### Alternatives Considered

FSIS announced its plan to prohibit the use of air-injection stunning of cattle in its current thinking paper on BSE, made available to the public on January 17, 2002 (67 FR 2399, Ref. 11 available for viewing by the public in the FSIS docket room and on the Internet at [http://www.fsis.usda.gov/OA/topics/BSE\\_thinking.htm](http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm)). Thus, although

generally the Agency neither promotes nor bans specific types of technology used for meat and poultry slaughter, the regulatory approach adopted with this action of prohibiting air-injection stunners is consistent with earlier statements made by the Agency. In its BSE current thinking paper, FSIS requested comments on the policy options discussed in the document and received no comments that opposed banning the use of air-injection stunners on cattle.

In addition to the approach that was adopted, the Agency considered the alternative of establishing a performance standard that stunning equipment would be required to meet to be used on cattle, and the alternative of no rulemaking.

Under the first option, the Agency would have developed a CNS tissue emboli performance standard that stunners would be required to meet to be permitted to be used on cattle. The benefits of this option are that it is more consistent with FSIS regulatory policy than banning a specific technology, and that it would prevent all methods of stunning that do not comply with the performance standard from being used on cattle, not just air-injection stunning. Thus, this option would prevent the need to regulate individual pieces of equipment.

A potential problem with this option is that there are relatively few studies on stunning methods and CNS tissue emboli. Thus, the Agency was concerned that if it were to establish a CNS tissue emboli performance standard for cattle stunning devices at this time, further studies could reveal that the performance standard selected does not achieve the result intended by the Agency. Therefore, FSIS decided to prohibit the use of the stunning method that all available studies do conclude result in CNS tissue macro-emboli, i.e., stunning that uses air-injection.

Establishing a CNS tissue emboli performance standard would also be more difficult to enforce than the option that was chosen because inspectors would be required to verify that the performance standard





was being met. Ensuring compliance with a CNS tissue emboli performance standard could involve analysis of blood or tissue samples for CNS tissue, either by the Agency or the establishment. On the other hand, enforcing a ban on air-injection stunners would simply involve visual verification that a certain piece of equipment is not being used. Thus, enforcement of a performance standard would require more resources than enforcement of an outright ban on air-injection stunners.

FSIS rejected the option of no rulemaking because, as previously mentioned, USDA action with regard to BSE has been, and should continue to be, proactive and preventive. Thus, the Agency is taking this action to strengthen its BSE prevention programs. Furthermore, the Agency has already publicized its intention to prohibit the use of air-injection stunning on cattle. There have been no developments with regard to this issue that justify a change in this position.

FSIS chose the option of prohibiting the use of air-injection stunning for cattle because the Harvard risk assessment and other recent studies indicate that of all the stunning devices that have been used on cattle in the U.S., pneumatic-powered captive bolt stunners that inject compressed air present the highest risk of exposing humans to bovine CNS tissue. Furthermore, unlike a performance standard, this option also clearly establishes which stunning methods would be prohibited, and it is easy to enforce. In addition, an outright prohibition on air-injection stunning is consistent with international laws and policies that did not allow the use of specific stunning technologies, such as air-injection.

#### Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This interim final rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 must be exhausted before any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA.

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#### Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this direct final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

#### Public Notification and Request for Data

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this direct final, FSIS will announce it and make copies of this Federal Register publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS Web page located at <http://www.fsis.usda.gov>



The update is used to provide information regarding

FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and Web page, FSIS is able to provide information to a much broader, more diverse audience. For more information contact the Congressional and Public Affairs Office, at (202) 720-9113. To be added to the free e-mail subscription service (Listserv), go to the ``Constituent Update'' page on the FSIS Web site at <http://www.fsis.usda.gov/oa/update/update.htm>. Click on the

``Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

#### References

The following sources are referred to in this document. All have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday.

1. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.

2. Garland, T., Bauer, N., Bailey, M., 1996. Brain emboli in the lung of cattle after stunning. *The Lancet*, 348:610.

3. Schmidt, G.R., Hossner, K.E., Yemm, R.S., Gould, D.H., 1999. Potential for disruption of central nervous system tissue in beef cattle by different types of captive bolt stunners, *J. Food Prot.*, 62:390-393.

4. Anil, M.H., Love, S., Williams, S., Shand, A., McKinstry, J.L., Helps, C.R., Waterman-Pearson, A., Seghatchian, J., and Harbour, D.A., 1999. Potential contamination of beef carcasses with brain tissue at slaughter. *Vet. Rec.*, 145: 460-462.

5. Munro, R. 1997. Neural tissue emboli in cattle. *Vet. Rec.*, 145:356.

6. Horlacher, S., Lucker, E., Eigenbrodt, E., Wenisch, S., 2002. ZNS-Emboli in der Rinderlunge (Brain emboli in the lungs of cattle). *Berl Munch Tierarztl Wochenschr* Jan-Feb; 115(1-2):1-5.

7. E.C. (European Commission), 2002. Opinion of 10-11 January 2002 of the Scientific Steering Committee on Stunning Methods and BSE Risks (The Risk of Dissemination of Brain Particles into the Blood and Carcass When Applying Certain Stunning Methods).

8. E.C. (European Commission), 2001. Report on Stunning Methods and BSE Risks (The Risk of Dissemination of Brain Particles into the Blood and Carcass When Applying Certain Stunning Methods). Prepared by the TSE BSE Ad Hoc Group at its meeting of 13 December 2001.

9. Mackey, B.M., and Derrick, C.M., 1979. Contamination of the deep tissues of carcasses by bacteria present on the slaughter instruments on in the gut. *J. Appl. Bact.*, 46:355-366.

10. USDA Agricultural Statistics, 2002, VII-44, Table 7-70.

11. Food Safety and Inspection Service (FSIS), Current Thinking On



Measures That Could Be Implemented To Minimize Human Exposure To Materials That Could Potentially Contain the Bovine Spongiform Encephalopathy Agent, January 15, 2002. Available on the internet at [http://www.fsis.usda.gov/OA/topics/BSE\\_thinking.htm](http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm).

#### List of Subjects

##### 9 CFR Part 310

Animal diseases, Meat inspection.

##### 9 CFR Part 313

Animal welfare, Livestock, Meat inspection.

0

For the reasons discussed in the preamble, FSIS amends 9 CFR chapter III as follows:

#### PART 310--POST-MORTEM INSPECTION

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1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

#### Sec. 310.13 [Amended]

0

2. Section 310.13 is amended as follows: Paragraph (a)(2)(iv)(C) is amended by adding the phrase ``of all livestock except cattle'' after ``into the skull'' and before ``in conjunction with''.

#### PART 313--HUMANE SLAUGHTER OF LIVESTOCK

0

1. The authority citation for part 313 continues to read as follows:

Authority: 7 U.S.C. 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

#### Sec. 313.15 [Amended]

0

2. Section 313.15 is amended as follows:

Paragraph (b)(2) is amended by revising the paragraph heading, designating the text as paragraph (b)(2)(i), and by adding a new paragraph (b)(2)(ii). The added and revised text reads as follows:

Sec. 313.15 Mechanical; captive bolt.

\* \* \* \* \*

(b) \* \* \*





(2) Special requirements and prohibitions.

\* \* \* \* \*

(ii) Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle.

Done at Washington, DC, on: January 7, 2004.

Garry L. McKee,

Administrator.

[FR Doc. 04-624 Filed 1-8-04; 1:43 pm]







# Appendices





## Q&As





Food Safety and Inspection Service  
United States Department of Agriculture  
Washington, D.C. 20250-3700

## Frequently Asked Questions

Updated January 14, 2004

# FSIS Further Strengthens Protections Against Bovine Spongiform Encephalopathy (BSE)

## Are all cattle inspected prior to slaughter?

All cattle slaughtered in federally inspected establishments in the United States are subject to inspection. FSIS inspectors examine cattle to identify any symptoms of disease, including signs of central nervous system impairment. Cattle that are suspect for any reason are examined by an FSIS veterinarian to determine whether the animal is eligible for slaughter.

Cattle that show signs of systemic illness and disease are condemned and not allowed into the human food supply. The brains from animals that exhibit signs of neurological impairment during inspection are submitted for testing and analysis by the USDA's National Veterinary Services Laboratories.

## What kind of testing does USDA do for BSE?

USDA's surveillance program for BSE draws samples of high-risk cattle that are then tested for BSE. More information on testing for BSE is available from the USDA's Animal and Plant Health Inspection Service (APHIS) at [www.aphis.usda.gov](http://www.aphis.usda.gov).

Effective December 30, 2003, carcasses from cattle intended for human food that are sampled and submitted to APHIS for BSE testing will be held until the sample is determined to be negative for BSE.

## What animals will be affected by the new policy?

Effective December 30, 2003, USDA will not allow any non-ambulatory disabled cattle to be slaughtered for human food. Non-ambulatory disabled cattle are animals that cannot rise from a recumbent position or that are disabled (e.g., have a broken appendage).

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## What are Advanced Meat Recovery systems?

Advanced Meat Recovery (AMR) is a technology that removes muscle tissue from the bone of carcasses under high pressure. The AMR process cannot be operated in a manner to incorporate central nervous system tissue (e.g., spinal cord) or excessive amounts of bone solids (measured by calcium level), or bone marrow (measured by iron level). The product resulting from the AMR process is meat.

**What products typically contain AMR as an ingredient?**

AMR products are usually blended with ground products derived from beef or pork trimmings. AMR is used in meat patties, links, sausages, chili products, sauces, soup bases, meat gravies, broth and flavorings.

**Is spinal cord allowed in meat, or specifically, product produced by AMR systems?**

FSIS policy gives a clear definition of meat (9 CFR 301.2 and 318.24) that does not include brain, trigeminal ganglia, spinal cord tissue, or dorsal root ganglia, all of which are central nervous system-type tissues. Therefore, product containing spinal cord tissue is not allowed to be called meat.

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**Does the new regulation affect this policy?**

Yes. The new regulation amends the previous definition of meat to emphasize that in addition to spinal cord, brain, trigeminal ganglia, and dorsal root ganglia tissue are not permitted in meat.

**Will FSIS test product produced by AMR systems for spinal cord tissue and dorsal root ganglia?**

Yes. In March 2003, FSIS began a routine regulatory sampling program to ensure that plants using AMR systems are preventing spinal cord from entering the food supply in products labeled as meat. The sampling program will be expanded to also test for the presence of dorsal root ganglia, and will include meat from beef and pork. Currently, there is no lamb prepared using AMR systems.

**What actions will FSIS take if spinal cord or dorsal root ganglia are found in product produced by AMR systems?**

Establishments must ensure that bones going in to the AMR system do not contain fragments of brain, trigeminal ganglia, or spinal cord. In addition, the product exiting the system cannot have spinal cord or dorsal root ganglia. If FSIS observes any bones entering the AMR system with these central nervous system-type tissues, the product that is produced will not be allowed to be labeled as meat. In addition, if tests on the product exiting the AMR system identify the presence of spinal cord or dorsal root ganglia, inspection personnel will withhold marks of inspection from the establishment's AMR product and tag the AMR system itself, meaning neither the product nor the equipment can be used until satisfactory corrective action has been taken. If the establishment has distributed the sampled product then the product will be subject to recall.

Inspection personnel conduct follow-up sampling to verify that the establishment has taken appropriate corrective action. AMR production will not be allowed to resume until FSIS determines that corrective actions have been successful.

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**What are Specified Risk Materials?**

Specified Risk Materials (SRMs) include the brain, skull, eyes trigeminal ganglia, spinal cord, vertebral



column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of cattle 30 months of age and older. SRMs also include the tonsils and distal ileum of all cattle. However, in order to ensure that the distal ileum is removed, the entire small intestine shall be removed.

### **Why is USDA banning SRMs?**

Science indicates that in animals with BSE, these materials harbor the infectious agent before the animal shows any clinical signs of disease. Canada took similar actions when a single case of BSE was discovered there in May 2003.

### **Have these materials been present in beef products produced before this ban?**

Brain and a portion of the small intestine could have been in products, but only if the product label indicated that these materials were present. Very few products contained these components. Tonsils have never been allowed in a meat product. Spinal cord tissue could only have been present in edible rendering.

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### **How will FSIS ensure that these SRMs are not present in human food?**

Slaughter and processing establishments will be required to develop procedures to show that SRMs are removed from product. To ensure that SRMs are not present in meat, FSIS inspectors will verify that establishments are properly removing these tissues. In addition, FSIS will continue a strong regulatory verification testing program of product produced from AMR systems to ensure that spinal cord and dorsal root ganglia are not present in meat.

Also, because vertebral column and the skull of cattle older than 30 months will be considered inedible, these materials cannot be used in AMR systems.

### **What is captive bolt air-injection stunning and why is USDA banning its use?**

Captive bolt stunning devices that inject air into the cranial cavity to stun cattle prior to slaughter can force visible pieces of central nervous system tissue into the circulatory system of cattle. This could present a risk of spreading BSE should it be present.

While no U.S. plants currently use air-injection stunning, by issuing this rule, FSIS will address the potential risk associated with imported products by prohibiting the import of beef products from foreign establishments that may use this stunning method.

### **What authority does FSIS have to amend these policies?**

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FSIS issues regulations governing the production of meat and meat food products prepared for distribution in commerce.

Under the FMIA, a meat food product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)) or if it is for any

reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m) (3)).

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See Also: [Frequently Asked Questions, Bovine Spongiform Encephalopathy “Mad Cow Disease”](#)

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**For Further Information Contact:**

- Media Inquiries: (202) 720-9113
- Congressional Inquiries: (202) 720-3897
- Constituent Inquiries: (202) 720-9113
- Consumer Inquiries: Call the USDA Meat and Poultry Hotline at 1-888-MPHotline; TTY: 1-800-256-7072.

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Food Safety and Inspection Service  
United States Department of Agriculture  
Washington, D.C. 20250-3700

## Frequently Asked Questions

Updated January 14, 2004

# Bovine Spongiform Encephalopathy "Mad Cow Disease"

## Are BSE and "mad cow disease" the same thing?

Yes. BSE stands for bovine spongiform encephalopathy, and it is widely referred to as "mad cow disease." It is a chronic degenerative disease that affects the central nervous system of cattle. BSE is named because of the spongy appearance of the brain tissue of infected cattle examined under a microscope.

## Is BSE related to any other diseases?

BSE belongs to a family of diseases known as the transmissible spongiform encephalopathies (TSEs). TSE animal diseases found in the United States include scrapie in sheep and goats, chronic wasting disease in deer and elk, transmissible spongiform encephalopathy in mink, feline spongiform encephalopathy in cats, and in humans: kuru, both classic and variant Creutzfeldt-Jakob disease, Gerstmann-Straussler-Scheinker syndrome, and fatal familial insomnia.

(Note: The one case of variant Creutzfeldt-Jakob disease in the United States is in a young woman who likely contracted the disease while living in the United Kingdom. Symptoms appeared after she moved to the United States. The Centers for Disease Control and Prevention has not found additional cases in the United States through its surveillance program.)

## What causes BSEs and other TSEs?

The agent that is responsible for BSE and other TSEs has not been fully characterized. Although other types of agents have been implicated, the theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as a cellular prion protein. The TSE agents are extremely resistant to heat, ultraviolet light, ionizing radiation, normal sterilization processes, and common disinfectants that normally inactivate viruses and bacteria.

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## What about the possibility of BSE coming from other TSEs already in the United States, such as deer and elk with chronic wasting disease, or other sources such as the practice of feeding cattle parts to pigs?

As mentioned before, there are several TSEs in the United States. However, there is no evidence to date that BSE has emanated from TSEs in other animals.

Regarding feeding practices, it is known that cattle can become infected with BSE by eating feed contaminated with the infectious BSE agent. This is why in 1997 the U.S. Food and Drug Administration (FDA) prohibited the use of most mammalian protein in the manufacture of animal feed intended for cattle and other ruminants. For additional information on the feed ban, visit [FDA's Center for Veterinary Medicine Web site at http://www.fda.gov/cvm/](http://www.fda.gov/cvm/).

### Where is the BSE agent found in cattle?

Current scientific research confirms that BSE infectivity occurs in the brain, trigeminal ganglia, tonsils, spinal cord, dorsal root ganglion, and distal ileum of the small intestine of cattle experimentally infected with the BSE agent. Research also confirms that BSE infectivity is in the brain, spinal cord, and retina of the eyes of cattle infected with the agent under field conditions. Although bone marrow has demonstrated infectivity in experimentally infected cattle, these findings are not conclusive.

### Can BSE be transmitted from one cow to another cow?

No. BSE is not a contagious disease. There is no evidence that the disease is transmitted through direct contact or animal-to-animal spread. The primary means by which animals become infected is through consumption of feed contaminated with the infectious BSE agent.

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### What is FSIS doing to protect the public from BSE?

While FSIS believes that the food supply is safe, the Agency has taken a number of steps to ensure that the public does not receive product that could have the BSE infectious agent – however remote that risk is to begin with. On December 23, 2003, after the discovery of a presumptive positive of BSE found in a Holstein dairy cow slaughtered at an establishment in Moses Lake, Washington (see [recall release FSIS-RC-067-2003](#)), FSIS immediately issued a press release that announced the firm's voluntary recall of 10,410 pounds of raw beef. This product might have been exposed to tissues containing the infectious agent that causes BSE. The recall was made out of an abundance of caution, since muscle meat does not contain the high risk neural tissues such as brain and spinal cord, and is considered safe.

In addition, on December 30, 2003, Agriculture Secretary Ann Veneman announced new policies that would further strengthen an existing solid food safety system against BSE. On that date, an immediate ban was enacted to prevent all non-ambulatory disabled cattle from being used in the human food supply. This group contains the highest risk population of cattle that could possibly have BSE. However, even before this ban, FSIS inspectors at slaughterhouses were condemning all cattle they suspected of showing central nervous system disorders.

The four policies that Secretary Veneman announced on December 30, 2003 were made effective by FSIS on January 12, 2004. These included:

- **Product Holding** – FSIS inspectors no longer mark cattle tested for BSE as “inspected and passed” until confirmation is received by FSIS and the plant that the cattle have, in fact, tested negative for BSE.
- **Specified Risk Material** – FSIS declared that skull, brain, trigeminal ganglia, eyes, vertebral column,



spinal cord and dorsal root ganglia of cattle 30 months of age or older and the small intestine of all cattle are specified risk materials that are *prohibited* in the human food supply. Tonsils from all cattle are also not allowed in the human food supply.

- **Advanced Meat Recovery** – FSIS expanded a prior prohibition on spinal cord from being allowed in product produced from a technology called advanced meat recovery (AMR). This new regulation prohibits dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebral column, in addition to spinal cord tissue from being in AMR product.
- **Air-Injection Stunning** – FSIS banned the practice of air-injection stunning to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of humanely stunning cattle during the slaughter process.

FSIS has implemented these measures as further safeguards in an existing strong food safety infrastructure to protect public health. For more information about these regulations, visit FSIS' Web page at: <http://www.fsis.usda.gov/oa/news/2004/bseregs.htm>.

### Is there a BSE test for meat?

No. The only USDA approved testing for the agent is post-mortem analyses of brain tissue. This is a laboratory screening test for BSE.

### How does one test for BSE?

Currently, there is no test to detect the disease in a live animal or in muscle meat. Veterinary pathologists confirm BSE by postmortem microscopic examination of brain tissue using sophisticated laboratory techniques, such as a histopathological examination to detect sponge-like changes in the brain tissue and immunohistochemistry to examine the BSE fibrils. These are "gold-standard" tests, and they take more than a week to run.

More rapid tests that provide results within 36 to 48 hours have been developed to detect the abnormal prion in brain or spinal cord tissue of dead animals. Rapid tests can be used to determine if BSE exists in a population and to obtain an indication of its prevalence or detect animals with the disease which are not yet showing clinical signs.

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### What are the clinical signs that cattle have BSE?

Cattle affected by BSE experience progressive degeneration of the nervous system. Affected animals might display changes in temperament, such as nervousness or aggression, abnormal posture, incoordination and difficulty in rising, decreased milk production, or loss of body weight despite continued appetite.

### Is there any cure for BSE?

No. There is no treatment for BSE. The course of the disease varies from two weeks to 14 months, usually resulting in death or humane destruction within four months in countries where the disease is present.

**How long can BSE be in an animal before it shows signs of the disease?**

The incubation period (the time from when an animal becomes infected until it first shows disease signs) is from 30 months to eight years with only a few rare exceptions in younger animals. Following the onset of clinical signs, the animal's condition deteriorates rapidly. This process usually takes from two weeks to six months. Most cases in Great Britain occurred in dairy cows between three and six years of age.

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**Are humans susceptible to BSE? \***

Although not scientifically proven, there is strong epidemiologic and laboratory data linking a rare, degenerative, fatal brain disorder in humans called variant Creutzfeldt-Jakob Disease (vCJD) to the consumption of BSE-contaminated product. This type of disease begins primarily with psychiatric symptoms and affects younger patients (median age, 28 years).

**How many cases of vCJD have there been and have there been any in the United States? \***

As of December 1, 2003, a total of 153 cases of vCJD had been reported in the world: 143 from the United Kingdom, six from France, and one each from Canada, Ireland, Italy, and the United States.

(Note: The one case of variant Creutzfeldt-Jakob disease in the United States is in a young woman who likely contracted the disease while living in the United Kingdom. Symptoms appeared after she moved to the United States. The Centers for Disease Control and Prevention has not found additional cases in the United States through its surveillance program.)

**How is variant Creutzfeldt-Jakob Disease different from classic Creutzfeldt-Jakob Disease? \***

The classic form of Creutzfeldt-Jakob Disease is endemic throughout the world, including the United States. The median age at death of patients with classic CJD in the United States is 68 years, and very few cases occur in persons under 30 years of age. In contrast, the median age at death of patients with vCJD is 28 years.

The vCJD can be confirmed only through examination of brain tissue obtained by biopsy or at autopsy, but a "probable case" of vCJD can be diagnosed on the basis of certain clinical criteria developed in the United Kingdom. The incubation period for vCJD is unknown because it is a relatively new disease. However, it is likely that ultimately this incubation period will be measured in terms of many years or decades. In other words, if a person develops vCJD from consuming a BSE-contaminated product (not yet scientifically proven), he or she likely would have consumed that product a decade or more earlier.

In contrast to classic CJD, vCJD predominantly affects younger people, has atypical clinical features, with prominent psychiatric or sensory symptoms at the time of clinical presentation. There are delayed onset of neurological abnormalities, including ataxia within weeks or months, dementia and myoclonus late in the illness. Typically, the duration of illness is at least six months.

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**Can BSE be transmitted to milk and other dairy products?**

There is no scientific evidence to suggest that milk and dairy products carry the agent that causes BSE.

### **What do I do if I ate recalled meat associated with BSE?**

The recalled meat (class II from December 23, 2003) is considered safe by USDA, as the tissues that would carry the BSE agent were completely removed at slaughter and not used in meat cuts or products that might have been consumed by humans. The recall from December 23, 2003 was made out of an abundance of caution. If you have concerns that you might have contracted a foodborne illness, then you should contact your health care provider.

### **Will cooking (including microwave cooking) kill the BSE agent?**

Current scientific research indicates that cooking will not kill the BSE agent.

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### **Will irradiation kill the BSE agent?**

Current scientific research indicates that irradiation will not kill the BSE agent.

### **Are baby foods safe?**

Beef products processed by mechanical separation may *not* be used in the formulation or production of baby, junior, or toddler foods.

Advanced meat recovery (AMR) products, which are processed by removing muscle tissue without breaking bones and do not include spinal cord tissue, is allowable for these products (However, there are further prohibitions of material allowed in AMR. See FSIS' [rule](#) which became effective January 12, 2004).

### **Are meats used in the National School Lunch Program safe?**

**Yes.** USDA's Agricultural Marketing Service (AMS), by specification, does not allow beef that is mechanically separated from bone with automatic deboning systems, advanced lean (meat) recovery (AMR) systems, or powered knives for any commodity programs. USDA procurement specifications for beef specifically prohibit the use of meat from downer animals – animals too sick or injured to walk.

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**For questions concerning animal feed for livestock or pets, contact the U.S. Health and Human Service's Food and Drug Administration (FDA).**

Center for Veterinary Medicine  
7519 Standish Place  
Rockville Maryland 20855-0001  
(301) 827-3800 or 1-888-INFO-FDA  
<http://www.fda.gov/cvm/>



**For questions concerning animal health, surveillance, and BSE, contact the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS).**

USDA-APHIS  
4700 River Road  
Riverdale, MD 20737  
(301) 734-7799  
<http://www.aphis.usda.gov/>

**\* For questions concerning vCJD or CJD, or any of the specific human diseases and technical terms mentioned on this Web page, contact the U.S. Health and Human Service's Centers for Disease Control and Prevention (CDC).**

Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30333  
(404) 639-3534  
(800) 311-3435  
<http://www.cdc.gov>

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 [See Also: Frequently Asked Questions, FSIS Further Strengthens Protections Against Bovine Spongiform Encephalopathy \(BSE\)](#)

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**For Further Information Contact:**

- Media Inquiries: (202) 720-9113
- Congressional Inquiries: (202) 720-3897
- Constituent Inquiries: (202) 720-9113
- Consumer Inquiries: Call the USDA Meat and Poultry Hotline at 1-888-MPHotline; TTY: 1-800-256-7072.

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# USDA BSE Chronology





## CASE OF BSE IN THE UNITED STATES CHRONOLOGY OF EVENTS

[Back to BSE Information and Resources](#)

December 9, 2003	A non-ambulatory dairy cow believed to be about 4-1/2 years old arrives at Verns Moses Lake Meats, a slaughter plant in Moses Lake, WA; the animal's condition is attributed to complications from calving. Consistent with USDA's standard testing protocols for BSE, samples are taken from the animal and all potential high-risk material (central nervous system tissue) is diverted out of the human food supply and into rendering.
December 11	Samples from the animal arrive at USDA's National Veterinary Services Laboratories (NVSL) in Ames, IA. Because the animal had no neurological signs at slaughter, it was not considered to be a higher priority for BSE and the samples were placed in the normal queue for testing.
December 22	Preliminary test results are positive for BSE; NVSL conducts further testing.
December 23	Further test results are positive for BSE. Secretary Veneman announces a "presumptive positive" case for BSE. A sample from the animal is hand-carried to the United Kingdom for final confirmatory testing at the BSE world reference laboratory in Weybridge, England.
	APHIS' epidemiological investigation begins. Quarantine placed on herd in Mabton, WA, in which the index animal had last resided.
December 23	USDA's Food Safety and Inspection Service initiates a Class II recall of meat (10,410 pounds) from the group of 20 animals slaughtered on December 9 at Verns Moses Lake Meats.
	USDA determines disposition of three calves from index animal: one died

	<p>shortly after birth in October 2001. One is a yearling heifer and is in the index herd in Mabton, WA, which is under State quarantine. The third is the most recently born calf, a bull calf, and is in a herd in Sunnyside, WA, which is placed under State quarantine</p>
December 25	<p>UK world reference laboratory confirms USDA diagnosis of BSE.</p> <p>Traceback of index animal continues. It is believed likely that the index animal was purchased into Mabton herd from a dairy cattle finishing farm in Mattawa, WA. The other, less likely, possibility is that it came from an area livestock market.</p>
December 27	<p>USDA's traceback investigation indicates that the affected cow was likely imported from Canada in 2001 and that she was likely 6-1/2 years old, rather than 4-1/2 years old as the last owner's records had indicated. Investigative efforts continue and involve Canadian officials.</p> <p>USDA team departs Washington for Japan to pursue trade talks.</p>
December 28	<p>USDA's Food Safety and Inspection Service (FSIS) determines that two tertiary cosignees (the customers of Williamette Valley Meats) of the recalled beef products had limited further distribution to four other states, including Alaska, Montana, Hawaii and Idaho, as well as the U.S. territory of Guam. These areas are in addition to the primary distribution in Oregon and Washington, with some product shipped to Nevada and California. FSIS continues to trackback the distribution of any recalled meat to ensure compliance with the recall.</p> <p>Traceback of the index animal continues. USDA is also continuing to trace the 73 other cows that came in the same shipment.</p>
December 29	<p>USDA determines that records obtained from the owner of the index animal correspond with Canada's records indicating that this animal was approximately 6 1/2 years old at the time of slaughter. USDA is working with Canada to</p>



	<p>conduct DNA tests to verify that the correct animal has been identified.</p> <p>Tracebacks of the index animal, along with the 73 other cows from the same shipment, continues. USDA identifies 8 additional cows from the same herd in Canada as the index cow that may have entered the United States. USDA begins tracing these animals.</p> <p>FSIS determines that the recalled meat products were distributed to 42 locations from Interstate Meats and Willamette Valley Meats, with at least 80 percent of the products distributed to stores in Oregon and Washington. FSIS is verifying that these 42 distributors, along with the original distributors, are complying with requirements to notify their customers.</p>
December 30	<p>Agriculture Secretary Ann Veneman announces additional safeguards to bolster the U.S. protection system against BSE and to further protect public health:</p> <ul style="list-style-type: none"><li>• downer cattle and specified risk material and tissues will immediately be banned from the human food chain</li><li>• skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age and a portion of the small intestine of cattle of all ages are now considered specified risk materials and are prohibited from entering the human food supply</li><li>• any normal cattle, if they are targeted for BSE surveillance testing at slaughter, will no longer be marked as "inspected and passed" until confirmation is received that the animals have, in fact, tested negative for BSE</li><li>• dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebrae column, in addition to already-prohibited spinal cord tissue, will be prohibited in products labeled as "meat"</li><li>• the air-injection stunning of cattle will be prohibited</li></ul>

	<ul style="list-style-type: none"> <li>• mechanically separated meat in human food will be prohibited</li> <li>• a verifiable system of national animal identification will be immediately implemented (See <a href="#">USDA's 12/30/03 press release</a> for more specifics)</li> </ul> <p>Traceback of the index animal continues. USDA continues working closely with Canadian officials to conduct DNA testing of the index cow.</p> <p>Through the traceback of the index animal, USDA determines that 82 cattle (including the positive cow) were cleared for shipment into the United States. USDA is verifying the actual number that entered the United States and the location of each animal. Initial information from Canada suggested only 74 of the 82 cattle on the health certificate were shipped to the United States. However, since USDA cannot rule out the possibility that the other eight also came across the border, USDA is looking at import/export records, as well as on-farm records, for all remaining 81 cattle.</p>
December 31	<p>USDA continues to work with Canadian officials to verify the traceback of the index animal. USDA is working with Canada to conduct DNA tests in both countries. Testing is expected to begin this evening and results could be available as early as next week.</p> <p>Through the traceback investigation, USDA learns that the Canadian health certificate, dated August 28, 2001, lists 82 eartag numbers from cattle that were part of a herd dispersal in Alberta, Canada. One of those eartag numbers matches that number on the BSE-positive cow. Nine of the 82 are part of the index herd in Washington State. Currently, USDA has information that suggests that 81 of the 82 animals crossed the border into the United States. However, since USDA cannot rule out the possibility that all the animals came into the United States, USDA is looking at import/export records, as well as on-farm records, for all</p>

	<p>remaining 72 cattle.</p> <p>USDA appoints an international team of experts to review the Department's investigation and make national recommendations following the completion of the epidemiological investigation. The team will be similar to the group that conducted such a review in Canada.</p>
January 2	<p>USDA confirms that 81 of the 82 animals listed on the Canadian health certificate, which includes the eartag number for the index cow, entered the United States through Oroville, WA, on September 4, 2001.</p> <p>USDA has 11 of the 82 cattle definitely accounted for including:</p> <ul style="list-style-type: none"><li>• One is the index cow</li><li>• Nine are those known to be in the index herd</li><li>• One animal is on the Mattawa premises</li><li>• Also, USDA believes one animal may still be in Canada</li></ul> <p>Tracebacks of the other 70 animals continue. USDA has good leads on the whereabouts of many of these animals.</p> <p>USDA announces that three facilities are under hold orders during the epidemiological investigation. The first facility is the index herd, while the second is a nearby facility that has the index cow's recently born bull calf. The third facility is a dairy operation in Mattawa where one animal from the original herd of 82 is located.</p> <p>USDA and Canadian officials continue DNA tests to determine the identification of the index animal. Two USDA epidemiologists are in Canada to assist with the testing, while two Canadian epidemiologists are in the United States to assist with the DNA testing.</p> <p>USDA is working closely with industry to reposition its efforts to collect samples of high-risk animals for BSE surveillance testing on farms, at rendering facilities, and other locations.</p>

January 5	<p>USDA announces the decision to depopulate the bull calf operation in Sunnyside, Washington, that includes a calf born to the heifer infected with BSE prior to the heifer's slaughter this past December. There are approximately 450 cattle on the premises, and operations will proceed this week but will likely be dependent on weather conditions in the Mabton area. The calves will be transported to a currently unused slaughter facility.</p> <p>USDA will have animal care experts on hand at both the farm where the calves will be loaded and at the slaughter facility to ensure humane treatment of the animals. The animals will be euthanized according to American Veterinary Medical Association animal welfare euthanasia guidelines. No products from any of the slaughtered animals will enter the human food chain, nor will products be rendered.</p> <p>A USDA team departs Washington for Mexico to pursue trade talks.</p> <p>USDA and Canadian officials continue DNA tests to determine the identification of the index animal. Test results are expected sometime this week.</p> <p>USDA has 11 of the 82 cattle that were listed on the Canadian health certificate, including the index cow, definitely accounted for. USDA believes that one of the animals is still in Canada. Tracebacks of the other 70 animals continue. USDA has good leads on the whereabouts of many of these animals.</p>
January 6	<p>USDA announces that DNA evidence now helps to verify—with a high degree of certainty—that the BSE positive cow found in Washington State originated from a dairy farm in Alberta, Canada.</p> <p>USDA depopulates the bull calf operation outside Sunnyside, WA. Approximately 450 calves are transported from the farm to a designated slaughter facility and euthanized according to American Veterinary Medical Association humane</p>



	<p>guidelines. USDA officials secure the animal carcasses overnight.</p> <p>Other elements of the investigation, including animal tracebacks, continue on both sides of the border and may provide additional information. This includes the cattle feed investigation in Canada as well as the additional DNA testing.</p>
January 7	<p>USDA disposes of the carcasses of the depopulated calves by landfill. None of the carcasses entered the human food supply chain or were rendered.</p> <p>USDA locates another animal that came into the United States with the index cow, which is also located in a Mattawa, WA dairy herd. USDA has 12 of the 82 cattle listed on the Canadian health certificate definitely accounted for including:</p> <ul style="list-style-type: none"> <li>• The index cow</li> <li>• Nine known to be in the index herd</li> <li>• Two animals on a Mattawa premises</li> </ul> <p>USDA also believes that one of the animals listed on the health certificate remained in Canada and did not enter the United States.</p> <p>Tracebacks of the other 69 animals that entered the United States continues. USDA has good leads on the whereabouts of many of these animals.</p> <p>A Japanese delegation arrives in the United States to participate in trade talks.</p>
January 8	<p>USDA finishes disposal of the carcasses of the depopulated calves by landfill. None of the carcasses entered the human food supply or were rendered.</p> <p>USDA's Food Safety and Inspection Service (FSIS) has submitted three rules and one notice for publication in the Federal Register on Monday, January 12, 2003. The rules and notice are:</p> <ul style="list-style-type: none"> <li>• An interim final rule declaring that the Specified Risk Materials, the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age or older, and the small intestine of all cattle are specified risk materials, and prohibited in the food supply. (Tonsils were already excluded). These prohibitions will be effective</li> </ul>

	<p>immediately upon publication in the Federal Register. · An interim final rule expanding on the prohibition of central nervous system tissues in advanced meat recovery products. · A final rule to prohibit air injection stunning. · A notice announcing that FSIS inspectors will not mark ambulatory cattle that have been targeted for BSE surveillance testing as "inspected and passed" until negative test results are obtained.</p>
January 9	<p>USDA announces it will begin accepting license applications for BSE tests. Heretofore, USDA's Center for Veterinary Biologics has been accepting and reviewing data from companies that have various rapid tests, but has not formally accepted applications for licensing. USDA announces it will soon begin to remove a limited number of cows from the index herd in Mabton, Washington. At this time, USDA will most likely remove approximately 130 animals from this herd that contains approximately 4,000 dairy cows. To summarize results thus far from the epidemiological investigation:</p> <p>Of the 81 cows that came from Canada with the positive cow:</p> <ul style="list-style-type: none"> <li>· One is the positive cow</li> <li>· Two are under a hold order at a premises in Mattawa</li> <li>· USDA believes 7 may have gone to another dairy and is working to determine if those animals are still there</li> <li>· Nine are in the index herd</li> <li>· Potentially some of the remaining cows that came in that shipment are on the index premises, but at this time the identity of these animals has not been confirmed.</li> </ul>
January 10	<p>USDA personnel begin a selective depopulation of the index herd. Nine animals from the index herd are transported, humanely euthanized, and sampled.</p>
January 12	<p>FSIS' new rules on product holding, specified risk material, advanced meat recovery, and air injection stunning become effective. USDA has traced a third animal to the herd in Mattawa, Washington. Two animals were previously traced to this herd. The three animals in the Mattawa herd will be removed. ]A</p>



	<p>declaration of extraordinary emergency, signed by Secretary Veneman, is published in the Federal Register. This declaration of extraordinary emergency authorizes the Secretary to (1) hold, seize, treat, apply other remedial actions to, destroy (including preventative slaughter), or otherwise dispose of, any animal, article, facility, or means of conveyance if the Secretary determines the action is necessary to prevent the dissemination of BSE and (2) prohibit or restrict the movement or use within the State of Washington, or any portion of the State of Washington, of any animal or article, means of conveyance, or facility if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination of BSE.</p>
January 13	<p>USDA has confirmed that one animal has gone to a dairy in Quincy, Washington. USDA believes that as many as seven animals may have been sent to this facility; we are working to confirm how many may remain at this facility. The State has placed a hold on this facility in order to aid the investigation. Selective depopulation of the index herd continues. USDA plans to transport, humanely euthanize, and test approximately 130 animals in the index herd.</p>
January 14	<p>Selective depopulation of the index herd continues. To date, 89 animals from the index premises have been euthanized and tested. Results of the tests will be reported as soon as they are available.</p>
January 15	<p>USDA's investigation on the 81 cows that came from Canada continues. Five additional animals have been located at a facility located in Connell, Washington. The State has placed a hold on the facility in order to facilitate the investigation. In total, 19 of the 81 cows that came from Canada have been located. Selective depopulation of the index herd, which began on Saturday, January 10, is expected to be completed today. USDA plans to transport, humanely euthanize, and test a total of 129 animals in the index herd. To date, 119 animals from the index premises have been euthanized and</p>

	tested. To date, 28 samples have completed testing; results have been negative.
January 16	<p>USDA locates 3 animals that are part of a group of 17 heifers originally dispersed from the Canadian source herd in August 2001. The 3 animals were mentioned by Canada's chief veterinarian during the January 6, 2004, technical conference call with USDA's Dr. Ron DeHaven. The 17 animals are separate from the 81 animals that arrived in the United States from Canada along with the index animal. The 3 animals were found at the Quincy, Washington, dairy where 1 of the 81 animals has also been located.</p> <p>APHIS continues to work to determine whether the remaining 14 animals entered the United States. Delegations from Mexico and Canada meet with USDA officials in Washington, D.C. to discuss issues related to BSE.</p>
January 17	USDA begins selective depopulation operations on the facility in Mattawa.
January 18	USDA's investigation on the 81 cows that came from Canada continues. Three additional animals are located at a facility in Tenino, Washington, and one additional animal is found in Connell, Washington. Washington State places a hold on the Tenino facility in order to facilitate the ongoing investigation. In total, 23 of the 81 cows that came from Canada have been located. USDA completes the selective depopulation of 129 animals from the index herd. To date, 30 samples from the index herd have completed testing; results have been negative for BSE.
January 19	USDA completes selective depopulation operations on the facility in Mattawa, Washington. To date, USDA has transported and sampled a total of 39 animals from this facility. To date, 121 samples taken from the depopulated index herd have completed testing; results have been negative for BSE.
January 20	USDA personnel locate another animal that is part of a group of 17 heifers

originally dispersed from the Canadian source herd in August 2001. The animal was found at a Boardman, Oregon, facility. It is not unusual for an epidemiological investigation to cover multiple States. These 17 animals were mentioned by Dr. Brian Evans, Chief Veterinary Officer for Canada, in the January 6, 2004, technical briefing and are not part of the original 81 animals. APHIS investigators have now located four from this group of 17. Three others were located at the Quincy facility. Investigators are still determining whether the remaining 13 animals entered the United States. Selective depopulation operations on the facility in Mattawa and the index herd have been completed. USDA has transported and sampled a total of 39 animals from the Mattawa facility and 131 animals from the index premises. To date, 129 samples from the index herd have completed testing; results have been negative for BSE. Results from the Mattawa herd are not yet available. Senior U.S. government officials continue talks with trading partners and this week are meeting with officials in Japan, the Philippines, Hong Kong and South Korea to discuss BSE related issues.

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**Canadian Food Inspection Agency**  
**Liaison, Preparedness and Policy Coordination**

**REGULATIONS AMENDING THE HEALTH OF ANIMALS**  
**REGULATIONS**

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Agriculture and Agri-Food, pursuant to subsection 64(1) <sup>a</sup> of the *Health of Animals Act*<sup>b</sup>, hereby makes the annexed *Regulations Amending the Health of Animals Regulations*.

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<sup>a</sup> S.C. 1993, c. 34, s. 76

<sup>b</sup> S.C. 1990, c. 21

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*amendments*

**1. (1) The definitions "animal" and "farm or ranch" in section 172 of the *Health of Animals Regulations* are replaced by the following:**

"animal" means a bison, a bovine and an ovine. (*animal*)

"farm or ranch" includes a feed lot, a breeding herd, an artificial insemination unit or any other place where an animal has been since leaving its farm of origin. (*ferme ou ranch*)

**(2) Section 172 of the Regulations is amended by adding the following in alphabetical order:**

"bison" means an animal, other than an embryo or a fertilized egg, of the subspecies *Bison bison bison*, *Bison bison athabasca* or *Bison bison bonasus*. (*bison*)

"bovine" means an animal, other than an embryo or a fertilized egg, of the species *Bos taurus* or *Bos indicus*. (*bovin*)

"ovine" means an animal, other than an embryo or a fertilized egg, of the genus *Ovis*. (*ovin*)

**2. Section 175 of the Regulations is amended by adding the following after subsection (1):**

(1.1) Every person who applies, or causes the application of, an approved tag to an animal, or the carcass of an animal, shall ensure that the tag is for the species of that animal and is applied to the animal, or the carcass, for which the tag was issued under subsection 174(1).

**3. The Regulations are amended by adding the following after section 175:**

*Record-Keeping Requirement*

**175.1** (1) Subject to subsection (2), every operator of a farm of origin, or of a farm or ranch other than the farm of origin, who removes, or causes the removal of, an ovine 18 months of age or older from the farm of origin or from the farm or ranch other than the farm of origin shall keep a record of

(a) the identification number on the approved tag that is applied to the ovine;

(b) the date of removal;

(c) the reason for removal; and

(d) the name and address of the owner or person having the possession, care or control of the ovine at the destination to which it is removed.

(2) Subsection (1) does not apply to an ovine transported directly for slaughter to an establishment registered under the *Meat Inspection Act* or under an Act of the legislature of a province that provides for the inspection of ovine carcasses.

(3) Every operator of a farm of origin, or of a farm or ranch other than the farm of origin, who receives, or causes the reception of, an ovine for breeding purposes, shall keep a record of

(a) the identification number on the approved tag that is applied to the ovine;

(b) the date of reception; and

(c) the name and address of the owner or person who had the possession, care or control of the ovine at the farm or ranch from which it was removed.



(4) Every person who is required to keep a record under to this section shall keep the record for a period of at least five years.

**4. Section 176 of the Regulations is replaced by the following:**

**176.** Subject to section 183, no person shall remove, or cause the removal of, an animal from its farm of origin or from a farm or ranch other than its farm of origin unless the animal bears an approved tag issued under subsection 174(1) for the farm or ranch where the approved tag was applied to the animal.

**5. The heading before section 183 of the Regulations is replaced by the following:**

*Tagging Site, Community Pasture, Exhibition Site or Veterinary Clinic*

**6. (1) The portion of subsection 183(1) of the Regulations before paragraph (a) is replaced by the following:**

**183. (1)** Subject to subsection (5), a bison or a bovine may be moved from its farm of origin, without having an approved tag applied to it, to a site for the purpose of having an approved tag applied to the animal at that site if

**(2) Paragraphs 183(1)(b) to (d) of the Regulations are replaced by the following:**

(b) the operator of the farm of origin supplies the bison or bovine along with the approved tag issued to that operator under subsection 174(1);

(c) the bison or bovine is not mixed with any other person's animals that do not bear approved tags;

(d) the approved tag referred to in paragraph (b) is applied to the bison or bovine immediately after it is received at the site; and

**(3) The portion of paragraph 183(1)(e) of the Regulations before subparagraph (i) is replaced by the following:**

(e) the person who manages the site keeps records, and makes them available to the administrator on request, of enough information about the origin of the bison or bovines received there to enable their origin to be traced, including

**(4) Subsection 183(2) of the Regulations is replaced by the following:**

(2) Subject to subsection (6), a bison or a bovine may be moved from its farm of origin, without having an approved tag applied to it, to a

community pasture, exhibition site or veterinary clinic if

(a) the person who manages the community pasture, exhibition site or veterinary clinic has previously provided the administrator with a statement containing the name and address of the community pasture, exhibition site or veterinary clinic and an undertaking that the person will comply with the requirements of paragraph (b);

(b) the person who manages the community pasture, exhibition site or veterinary clinic keeps records, and makes them available to the administrator on request, of enough information about the origin of the bison or bovines received there to enable their origin to be traced, including

(i) the names and addresses of the owners or persons having the possession, care or control of the animals when they are brought to the community pasture, exhibition site or veterinary clinic,

(ii) the dates when the animals are brought to the community pasture, exhibition site or veterinary clinic,

(iii) the dates when the animals are removed from the community pasture, exhibition site or veterinary clinic,

(iv) the names and addresses of the owners or persons having the possession, care or control of the animals when they are removed from the community pasture, exhibition site or veterinary clinic, and

(v) the numbers of any approved tags that are applied to the animals at the community pasture, exhibition site or veterinary clinic and the dates when the approved tags are applied to the animals; and

(c) the bison or bovine is returned to its farm of origin at the end of the grazing season, exhibition or veterinary evaluation, as the case may be, or an approved tag for the animal's farm of origin is applied to the animal before it is removed from the community pasture, exhibition site or veterinary clinic.

**(5) Subsections 183(5) and (6) of the Regulations are replaced by the following:**

(5) If a person fails to comply with subsection (3), the Minister may order the person not to receive any bison or bovines at the site referred to in subsection (1) for the purpose of applying approved tags to them at that site.

(6) If a person fails to comply with subsection (4), the Minister may order the person not to receive any bison or bovines at a community pasture, exhibition site or veterinary clinic unless the animals have approved tags



applied to them.

**(6) Subsection 183(10) of the Regulations is replaced by the following:**

(10) The Minister shall have the notice published in a newspaper of general circulation in the community where the site referred to in subsection (1) or the community pasture, exhibition site or veterinary clinic, as the case may be, is located.

**7. Paragraph 184(3)(c) of the Regulations is replaced by the following:**

(c) in the case of a bison or a bovine, the person who operates the abattoir reports to the administrator, within 30 days after the animal is slaughtered, the information that the person is required by paragraph (b) to record in respect of the animal.

**8. Paragraph 186(1)(b) of the Regulations is replaced by the following:**

(b) in the case of a bison or a bovine, shall report the death of the animal and the number of the approved tag to the administrator within 30 days after the death.

**9. Paragraph 188(1)(b) of the Regulations is replaced by the following:**

(b) in the case of a bison or a bovine, shall ensure that the number of the animal's approved tag is reported to the administrator, along with the number of any tag applied to the animal in place of the approved tag, within 30 days after the exportation.

**10. Paragraphs 189(2)(a) and (b) of the Regulations are replaced by the following:**

- (a) if a bison is being imported, within 60 days after importation;
- (b) if a bovine is being imported, within 30 days after importation; or
- (c) if an ovine is being imported, within 7 days after importation.

coming into force

**11. These Regulations come into force on January 1, 2004.**

Date Modified: 2003-12-31

  
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## Canadian Food Inspection Agency Liaison, Preparedness and Policy Coordination

### REGULATIONS AMENDING THE HEALTH OF ANIMALS REGULATIONS

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Agriculture and Agri-Food, pursuant to subsection 64(1)<sup>a</sup> of the *Health of Animals Act*<sup>b</sup>, hereby makes the annexed *Regulations Amending the Health of Animals Regulations*.

<sup>a</sup> S.C. 1993, c. 34, s. 76

<sup>b</sup> S.C. 1990, c. 21

### REGULATIONS AMENDING THE HEALTH OF ANIMALS REGULATIONS

#### amendments

**1. The *Health of Animals Regulations*<sup>1</sup> are amended by adding the following after section 6:**

#### PART I.1

#### SPECIFIED RISK MATERIAL

**6.1** In this Part, "specified risk material" means

(a) the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older; and

(b) the distal ileum of cattle of all ages.

**6.2** Every person who slaughters, cuts up or debones cattle for human consumption as food shall ensure that the specified risk material has

been removed from the cattle.

**6.3** No person shall use or export for human consumption as food specified risk material in any form, whether or not incorporated into another thing, where the specified risk material was removed from cattle slaughtered in Canada.

**2. The definition "import reference document" in section 10 of the Regulations is replaced by the following:**

"import reference document" means the document prepared by the Agency and entitled *Import Reference Document*, bearing the date June 20, 2003 and policy number AHPD-DSAE-IE-2002-3-1A and available on the Agency's web site or by requesting a copy from the Agency.  
(*document de référence*)

coming into force

**3. These Regulations come into force on the 31st day after the day on which they are registered.**

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<sup>1</sup>C.R.C., c. 296; SOR/91-525





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<sup>a</sup> S.C. 1993, c. 34, s. 76

<sup>b</sup> S.C. 1990, c. 21

### REGULATIONS AMENDING THE HEALTH OF ANIMALS REGULATIONS

#### amendments

#### 1. The *Health of Animals Regulations*<sup>1</sup> are amended by adding the following after section 91.1:

91.2 (1) Every laboratory that diagnoses or suspects the appearance in an animal or thing of a disease set out in Schedule VII shall notify the Minister immediately of the diagnosis or suspicion.

(2) Along with that notification, the laboratory shall include

- a. the name, address and telephone number of the person who owns or has the possession, care or control of the animal or thing;
- b. the location of the animal or thing; and
- c. all other information that the laboratory has in relation to the animal or thing.

(3) Every laboratory that diagnoses or suspects the appearance in an animal or thing of a disease set out in Schedule VIII shall notify the Minister of the diagnosis or suspicion immediately after the end of the calendar year in which the appearance of the disease is diagnosed or suspected.

**2. The Regulations are amended by adding the following after Schedule VI:**

**SCHEDULE VII**

*(Subsection 91.2(1))*

**IMMEDIATELY NOTIFIABLE DISEASES**

Item	Disease
1.	aino virus infection
2.	akabane disease
3.	avian chlamydiosis ( <i>C. psittaci</i> )
4.	avian encephalomyelitis
5.	avian infectious laryngotracheitis
6.	besnoitiosis
7.	Borna disease
8.	bovine babesiosis ( <i>B. bovis</i> )
9.	bovine ephemeral fever
10.	bovine petechial fever
11.	contagious agalactia
12.	contagious caprine pleuropneumonia
13.	dourine
14.	duck hepatitis
15.	egg drop syndrome (adenovirus)
16.	enterovirus encephalomyelitis (Teschén disease)
17.	epizootic haemorrhagic disease
18.	epizootic lymphangitis
19.	equine encephalomyelitis, western and eastern
20.	fluvalinate-resistant Varroa mite
21.	fowl cholera



22.	glanders
23.	goose parvovirus infection (Derzsy's disease)
24.	heartwater (cowdriosis)
25.	hendra virus
26.	herpes virus of cervidae
27.	Ibaraki disease
28.	Japanese encephalitis
29.	louping ill
30.	Nairobi sheep disease
31.	Nipah virus
32.	screwworm ( <i>Cochliomyia hominivorax</i> and <i>Chrysomya bezziana</i> )
33.	small hive beetle ( <i>Aethina tumida</i> )
34.	theileriasis
35.	tick-borne fever ( <i>Cytoecetes phagocytophilia</i> )
36.	tissue worm ( <i>Elaphostrongylus cervi</i> )
37.	trypanosomiasis (exotic to Canada)
38.	turkey viral rhinotracheitis or swollen head disease in chickens
39.	viral haemorrhagic disease of rabbits
40.	Wesselbron's disease
41.	West Nile fever

#### SCHEDULE VIII

(Subsection 91.2(3))

#### ANNUALLY NOTIFIABLE DISEASES

Item	Disease
1.	acarine disease
2.	actinomycosis
3.	American foul brood
4.	atrophic rhinitis
5.	avian infectious bronchitis
6.	avian leukosis
7.	avian salmonellosis

8.	avian spirochaetosis
9.	avian tuberculosis
10.	blackleg
11.	botulism
12.	bovine genital campylobacteriosis
13.	bovine malignant catarrhal fever
14.	bovine viral diarrhoea or mucosal disease
15.	caprine arthritis-encephalitis
16.	caseous lymphadenitis
17.	coccidiosis
18.	contagious ophthalmia
19.	contagious pustular dermatitis
20.	dermatophilosis
21.	distomatosis (liver fluke)
22.	duck virus enteritis
23.	echinococcosis or hydatidosis
24.	enterotoxaemia
25.	enzootic abortion
26.	enzootic bovine leucosis
27.	equine coital exanthema
28.	equine influenza
29.	equine rhinopneumonitis
30.	European foul brood
31.	filariasis
32.	foot-rot
33.	fowl pox
34.	haemorrhagic septicemia
35.	horse mange ( <i>Psoroptes equi</i> )
36.	equine viral arteritis
37.	infectious bovine rhinotracheitis (IBR or IPV)
38.	infectious bursal disease (Gumboro disease)
39.	infectious coryza
40.	intestinal salmonella infections
41.	listeriosis

42.	maedi-visna
43.	Marek's disease
44.	melioidosis
45.	avian mycoplasmosis ( <i>M. Gallisepticum</i> )
46.	myxomatosis
47.	nosematosis of bees
48.	other clostridial infections
49.	other pasteurelloses
50.	ovine epididymitis ( <i>Brucella ovis</i> )
51.	ovine pulmonary adenomatosis
52.	paratuberculosis (Johne's disease)
53.	porcine reproductive and respiratory syndrome (PRRS)
54.	Q fever
55.	<i>Salmonella abortus ovis</i>
56.	<i>Salmonella abortus equi</i>
57.	sheep mange (scab)
58.	strangles
59.	swine erysipelas
60.	toxoplasmosis
61.	transmissible gastroenteritis (TGE)
62.	trichomoniasis
63.	tularaemia
64.	ulcerative lymphangitis
65.	vibrionic dysentery
66.	warble infestation

coming into force

**3. These Regulations come into force on the day on which they are registered.**

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<sup>1</sup> C.R.C., c. 296; SOR/91-525

Date Modified: 2002-11-02

  
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Canadian Food  
Inspection Agency

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Ottawa, Ontario  
K1A 0Y9

July 24, 2003

**MEAT HYGIENE DIRECTIVE:**

**2003 - 18 (AMENDED)**

**SUBJECT:**

**Chapter 4: Provisions for the removal of Specified Risk Materials (SRM) from cattle carcasses slaughtered in establishments inspected under the *Meat Inspection Regulations***

**THIS IS AN AMENDED VERSION OF THE DIRECTIVE 2003-18 ON PROVISIONS FOR THE REMOVAL OF SRMS. EACH VETERINARIAN/INSPECTOR-IN-CHARGE IS REQUIRED TO IMMEDIATELY PROVIDE A COPY OF THIS DIRECTIVE TO THE OPERATOR OF THE CFIA INSPECTED ESTABLISHMENTS S/HE IS RESPONSIBLE FOR.**

This Directive describes the requirements for the removal, identification, control and disposition of Specified Risk Materials (SRM) from cattle carcasses to prevent tissues that may contain BSE infectivity from entering the human food chain.

This policy will become effective on July 24, 2003.

**CHAPTER 4 - ENGLISH VERSION:**

Please replace pages 19 to 24 of Chapter 4 of your copy of the Manual of Procedures with the attached new pages and add new Annex N.

**CHAPTER 4 - FRENCH VERSION:**

Please replace pages 21 to 26 of Chapter 4 of your copy of the Manual of Procedures with the attached new pages and add new Annex N.

Merv Baker  
Director  
Food of Animal Origin Division

Att./p.j.

Chapter 4 - Pages 19 - 24

Slaughtering floors shall have adequate hand-washing facilities, including hot and cold water, soap and towels. These facilities must be readily available to all butchers and inspectors engaged in handling reactors. Prompt and adequate first-aid treatment should be given to any employee who sustains a cut, no matter how minor, as such action can well prevent possible infection.

#### **(5) Stunning ratites (ostrich, rhea, emu)**

Shackling may be accomplished either before or after stunning. In either case, caution is advised to avoid injury to operators by the bird's legs.

Emus may be restrained by having an experienced person flip them on their back.

Antemortem inspection and stunning may occur on the truck or trailer, especially for non ambulatory birds. Ratites may be subdued prior to stunning by placing a bag over the head to exclude light. Carbon dioxide may be delivered through a fitted mask to effect what has been reported to be very effective stunning. Alternatively, stunning may be performed by either a blow on the apex of the skull using a captive bolt pistol or by a non-reversible electrical stunning device. When using an electrical stunning device, operators must ensure that the electrical current passes directly through the bird's brain at sufficient strength to ensure a non-reversible stun.

#### **4.4.6 Enforcement actions by inspectors**

Enforcement actions by inspection staff may be required in regard to delivery, pre-slaughter accommodation and handling, or stunning and slaughter of food animals.

##### **(1) Delivery of food animals to slaughterhouses**

Violations of transportation regulations, such as overcrowding, careless exposure to inclement weather, or any circumstance which has resulted in unnecessary suffering of food animals, shall be reported to the Regional Supervisor for further investigation. Veterinarians-in-charge shall collect and maintain as much evidence as possible in regard to such incidences. In case of court action such evidence is invaluable. Court action may be initiated by the Director, Food Inspection, in consultation with Departmental Legal Advisors.

##### **(2) Pre-slaughter accommodation and handling of food animals**

Unsatisfactory conditions concerning animal holding facilities shall be brought to the attention of plant management before they become critical. Request to plant management shall be documented with a copy to the Director, Food Inspection. The use of areas in serious violation of the requirements under the Meat Inspection Act and Regulations shall be stopped until they are brought up to standard.

Inhumane handling of food animals on the plant premises shall not be tolerated by an inspector.

In the event of lack of corrective action, enforcement action including halting of stunning and slaughter operations shall be taken.



### **(3) Stunning and slaughter of food animals**

The inspection staff shall monitor on an ongoing basis the stunning and slaughter of food animals. Whenever an inspector observes inhumane treatment of food animals either due to malfunction of stunning equipment or due to operator carelessness or incompetence, the inspector shall immediately halt stunning and slaughter operations until management of the slaughter plant has taken effective corrective action. Cases which cannot be resolved by the Veterinarian-in-Charge shall be referred to the Director, Food Inspection. In cases of non-cooperation, or flagrant violation of provisions of the Meat Inspection Regulations, legal action may be initiated.

### **4.5 Dressing procedures**

It is plant management's responsibility to ensure that all dressing procedures are conducted in a sanitary manner and result in non-adulterated meat products destined for human consumption or animal food. It is the responsibility of the inspection staff to monitor the plant employees' procedures.

Such procedures should not result in undue contamination of meat products, and all carcasses and parts presented for postmortem inspection should be clean and free from dressing defects. It cannot be overemphasized that inspection staff are not to perform dressing procedures; all manipulations of carcasses and parts by inspection staff are limited to determining the acceptability of the products and to controlling the separation of inedible meat product.

#### **4.5.1 Dressing procedures for cattle**

**Bovine Spongiform Encephalopathy (BSE):** Certain control measures must be implemented by all operators involved in the slaughter of cattle regardless of the age of the animal slaughtered as additional measures adopted by the Canadian government in order to prevent tissues that may contain BSE infectivity from entering the human food chain.

Refer to Annex N of this chapter for a description of applicable control measures.

#### **(a) Sticking and bleeding**

The "dry" landing area, where stunned animals are discharged from the knocking box, shall be kept as clean and as dry as possible. Sticking shall not occur in this area. The animals shall be promptly hoisted, conveyed to a properly constructed bleeding area, and then bled.

Sufficient space and time must be made available for bleeding so that blood will be confined to the bleeding area. The sticking knife shall be sanitized between each animal. Blood, intended for edible purposes, must be collected without contamination and shall be identified to the carcass. Any condition found on postmortem examination which requires total carcass condemnation makes it necessary to locate and condemn not only the head and organs but also the blood.

If blood from several animals is collected in one container, and one of the animals in the lot is condemned, all the blood collected in that particular container shall be condemned. The

equipment used for the collection of blood, which is done either on an individual or lot basis, shall be sanitized between each carcass or lot, as appropriate. Blood clotting is prevented by either using approved anti-coagulants or mechanical defibrination. The latter must be done with suitable metal or plastic beaters (not with hands), cleaned and sanitized after use.

Carcasses shall be spaced, from the bleeding area to the point of approval, in such a way as to prevent skinned carcasses contacting either unskinned or other skinned carcasses or parts.

### **(b) Head handling**

After a head is skinned, it should be removed from the carcass immediately, without the exposed surfaces becoming contaminated. A handwash facility and an equipment sanitizer shall be provided in the area where heads are removed from carcasses. The employee who removes heads shall wash his hands and sanitize his knives after each head removal.

Facilities shall be provided to ensure that heads do not come into contact with one another until after completion of inspection and disposition of the carcass.

The identity of heads shall be preserved until final disposition of corresponding carcasses.

Facilities shall be provided for the removal of horns and pieces of skin, which must be done prior to head washing. The equipment used for removing the horns must be easy to clean and sanitize to avoid carrying contamination from one head to another. Heads, including oral and nasal cavities, shall be thoroughly washed before making any further incision in the musculature. Head washing cabinets shall be connected directly into a drain. The tongue shall be dropped and the tonsils removed, before the head is presented for inspection. If additional rinsing of the buccal cavity is required to remove any remaining ingesta, this must be performed without splash contamination of other heads.

Cheek meat removed from the head shall be trimmed free of salivary glands and mucous membranes, then washed thoroughly and chilled as quickly as possible.

The tongue shall be removed from the head, trimmed, washed free of blood and chilled. Tongues shall be stamped with the Meat Inspection Legend before or after chilling. The harvesting of head meat and tongues is to be done only after the carcass has received approval. Head hooks shall be sanitized with 82EC water after every use.

### **(c) Esophagus rodding and tying**

The esophagus shall be rodded or otherwise separated from the surrounding tissues to prevent carcass contamination.

Rodding is required when abdominal viscera are to be removed separately from thoracic viscera. Rodding separates the esophagus from the trachea, lungs and surrounding tissue and permits removal through the diaphragm and thoracic cavity without rupture of the esophagus during evisceration. The rod shall be adequately rinsed and sanitized between carcasses.



To prevent contamination with rumen contents, the esophagus shall be effectively tied before evisceration.

#### **(d) Udder and penis removal**

Lactating udders shall be removed avoiding soilage of carcasses, facilities and equipment. Any carcass contamination must be trimmed off. The penis and prepuce must also be removed without contamination of the carcass.

Contaminated facilities and equipment must be washed and sanitized. Mammary lymph nodes shall remain on the carcass until the inspection is completed.

In the skinning and opening of reactor carcasses, extreme care must be exercised not to incise the udder, in order to prevent contamination of workmen, meat products and tools.

#### **(e) Feet and hide removal**

Ear tags (e.g. the Canadian Cattle Identification Agency (CCIA) official tags) shall be attached, after their insertion into a plastic bag, to the fore shank of the carcass following hide removal. Alternative procedures that assure, with equal confidence, maintenance of the identity of the carcass and all its parts until their final disposition is known, may be approved by the veterinarian in charge. It is a requirement under the Animal Identification provisions of the Health of Animals Regulations that the operator of a slaughter establishment where an animal bearing an approved tag (i.e. a tag as defined under the CCIA) is slaughtered maintain the identity of the animal's carcass until the carcass is approved for human consumption or is condemned. CFIA inspection personnel will monitor this procedure as part of verifying the controls the operator has in place to ensure the proper identification of the carcass and the correlation of the carcass and its parts.

#### **(i) Bed system**

After removing the head, the carcass may be placed on a skinning bed (floor or cradle). Care should be taken to avoid contamination of neck tissue. Exposed tissue must not contact the floor, cradle or outside skin surfaces.

The feet must be removed before the carcass is skinned. The hind feet are removed by skinning the area above and below the place where the leg is to be cut and thus removed without contacting the hide. The front feet are removed in such a manner as to avoid contamination of the carcass.

Feet harvested for edible purposes shall be identified with the carcass, and shall not be approved for human consumption until the carcass receives similar approval.

The skin shall be cut from inside-out to prevent carcass contamination with hair and dirt, except for the necessary starting cuts. The knife used to begin skinning operations must be washed and sanitized prior to re-use. The hair side of the hide should be carefully rolled or reflected away from the carcass during skinning.

When the carcass is being moved from the skinning bed, the exposed parts shall not contact

the floor, cradle or other contaminated objects, including the outer side of the skin, boots and aprons, etc. The floor in this area must be cleaned after each carcass by washing and, if contaminated with pus or other septic material, by sanitizing. Washing must not result in splash contamination.

A handwash station and sanitizer must be conveniently located for the use of the employees who skin and otherwise dress carcasses.

#### (ii) Rail system

The same sanitary skinning principles outlined for the bed system apply to the rail system.

Skinning should begin at the hind shanks after foot removal and proceed downward, reflecting the hide away from the carcass. If chains or other means of restraining the carcasses during hide removal are employed, these are to be sanitized between each carcass.

#### (iii) Hide handling

Regardless of the method employed for hide removal, the latter shall be removed immediately from the kill floor to the inedible section of the establishment without becoming a source of contamination. If a chute is employed, it shall be adequately baffled; if a doorway is used, it shall be equipped with automatic door closers.

#### (f) Brisket opening

Only a clean cleaver or saw shall be used to split the brisket. The cleaver or saw shall be sanitized after each use.

The brisket is opened to facilitate removal of organs from the thoracic cavity. Opening can be done before or after complete hide removal. If done before hide removal, the hide over the midline must be adequately reflected. In opening the brisket, care must be taken to avoid puncturing the viscera which invariably results in carcass contamination.

#### (g) Bung (rectum) dropping

During hide removal, a circular cut has been made around the anus, taking care to leave the anal sphincter intact. The subsequent cut freeing the anus and rectum from the surrounding tissue must be done with a clean knife. The rectum is then tied together with the neck of the bladder to prevent contamination and they are then dropped into the pelvic cavity.

#### (h) Evisceration

Any contamination shall be trimmed from the midline before opening the abdominal cavity. The opening should not result in carcass or viscera contamination.

The viscera shall be placed in a clean truck or on a clean table. If the viscera or carcass is condemned or the surface of a truck or stationary table is contaminated, the equipment must be sanitized with water of a minimum temperature of 82EC before reuse. Moving tables shall



be automatically cleaned and sanitized with water of a minimum temperature of 82EC. The temperature gauges shall be visible to the viscera inspector.

If carcasses are eviscerated onto a moving top table, the eviscerator is to wear clean rubber boots which are adequately identified (preferably white) and an apron. Another pair of boots or shoes must be used when leaving the table. The washing cabinet used by the eviscerator must be connected directly into a drain. Access to the table from the cabinet must be such that when the eviscerator leaves the cabinet he must step directly onto the clean, sanitized portion of the table or a clean stand, but never onto a contaminated table or platform. The eviscerating knife, boots, apron, etc., must be sanitized when contamination occurs.

The uro-genital organs such as bladder, ovaries and uterus, should be removed in total without incising them, following which they must be transferred to watertight metal containers or chutes for direct delivery to the inedible section. Extra care must be taken in the case of a brucellosis reactor.

There must be synchronization between carcass and viscera. Carcass, viscera and head identity must be maintained in all cases. The identity of feet and blood must also be maintained if saved for edible purposes. Pathological lesions shall not be removed (unless permitted by an inspector) until postmortem inspection is completed.

To prevent cross-contamination on the kill floor, the exposed carcass must not come in contact with stationary parts of the viscera table, any other uncleaned equipment on the kill floor (high bench, retaining bars, etc.) or any other carcass, prior to final carcass inspection.

While accidental contamination may occur, careless techniques are not acceptable. Contaminated carcasses must be trimmed, not washed. It is management's responsibility to satisfactorily dress carcasses. It is the inspection staff's responsibility to monitor the dressing procedures and insist that management takes appropriate action when and if necessary.

#### **(i) Electrical stimulation**

If an apparatus is employed to electrically stimulate carcasses before final inspection, then all parts of that equipment coming into contact with the carcass must be adequately sanitized after each use.

#### **(j) Carcass splitting**

To prevent contamination by the saw to other carcass surfaces, abscesses, grubs, grubby tissue or contamination shall be removed from the back of the carcass before splitting.

The splitting saw must always be sanitized after becoming contaminated or after splitting a held carcass.

#### **(k) Trimming**

Carcass trimming must be done in an area set aside for that purpose. Stick wounds, any residual piece of hide, blood clots, bruised tissue and contamination must be removed. Carcasses shall be checked for cleanliness by a company employee before washing. This

check shall be closely monitored by the inspection staff.

The spinal cord must be completely removed from split carcasses before the final carcass wash. The operator must implement a process control to make sure the removal is complete and consistent.

#### (l) Carcass washing

After trimming, all carcasses shall be washed to remove blood and bone dust. The pinning of the neck and shrouding may be done after trimming and washing of the carcass are completed.

#### **(m) Use of organic acid, chlorine, chlorine dioxide and acidified chlorine solutions on red meat carcasses:**

See subsection 4.5.3(e), titled "Application of microbial control agents", of this chapter for general requirements for using such agents on raw meat carcasses and parts. Additional requirements for red meat carcasses are as follows:

#### **Organic sprays**

The use of 1.5 - 2.5% acetic acid or lactic acid or citric acid washes on red meat carcasses is permitted as a processing aid under the following conditions.

(i) Organic acid solutions may be applied where it is accepted practice to apply water to product such as before, after or during the final carcass rinse. Pre-evisceration rinse systems consisting of a potable water rinse, and a second rinse with an organic acid are also permitted. The first rinse is applied as a low pressure water rinse to remove incidental foreign material. The second rinse, consisting of an aqueous solution of 1.5 - 2.5 percent organic acid, may be applied as a mist, fog or small droplet rinse.

(ii) The treatment must be followed by appropriate measures to ensure that any residues of the acids in question in or on the meat, resulting from the treatment are negligible. In practice this would involve a final rinse with potable water.

(iii) A documented description of the process and controls to monitor the concentration of the treatment solution and other necessary operating parameters be in place and available to CFIA inspection staff. This documentation should at least describe:

- the equipment used and methods to assure that fumes from the acid do not create a health hazard;
- type and concentration of acid used;
- formula for preparing acid solution;
- site and rate of application including solution flow rate and pressure;
- temperature of acid solution at point of contact;



- methods used to assure no residual acid is left on the surface of the carcass;
- a description of actions to be taken if the system is found to be operating out of compliance.

\* N.B. Trimming of the surface layers of the meat product or other such measures to remove surface residues of chemicals resulting from acid spray treatment have been suggested as an alternative to a potable water rinse.

### **Chlorine**

The same requirements apply as for organic acids (see above) except that a maximum of up to 20 ppm of total available chlorine may be contained in water contacting red meat carcasses or beef quarters.

### **Chlorine dioxide**

The same requirements apply as for organic acids (see above) except that a maximum of up to 20 ppm of total available chlorine dioxide may be contained in water contacting red meat carcasses.

### **Acidified chlorine**

The same requirements apply as for organic acids (see above) except that a maximum of up to 10 ppm of total available (acidified) chlorine may be contained in water contacting beef carcasses

## **4.5.2 Dressing procedures for swine**

### **(a) Bleeding**

Hogs presented for bleeding shall have been rendered unconscious by an approved method and shall be bled immediately following stunning. The stick wound shall be as small as possible and care should be taken to avoid shoulder sticking. The sticking of hogs not properly rendered unconscious is in direct violation of the Meat Inspection Act and Regulations.

## **CHAPTER 4 - ANNEX N**

### **REMOVAL OF SPECIFIED RISK MATERIALS (SRM) FROM CATTLE SLAUGHTERED IN ESTABLISHMENTS INSPECTED UNDER THE *MEAT INSPECTION REGULATIONS*, 1990**

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### APPENDIX B - DIAGRAMS: CATTLE VERTEBRAL COLUMN

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## DEFINITIONS

For the purposes of this policy:

**Cattle** means animals of the species *Bos taurus* or *Bos indicus*; but does not include other ruminants such as bison, muskox, yak or water buffalo.

**Specified Risk Materials (SRM)** mean the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older, and the distal ileum of cattle of all ages.

**Note:** The brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia are designated as SRM because, in Bovine Spongiform Encephalopathy (BSE) infected cattle, these tissues contain the BSE agent and may transmit the disease. The skull is designated as well because of the high probability of it becoming contaminated at the time of stunning and during manipulation of the other tissues if their separate removal was permitted.

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## 1.0 INTRODUCTION

The Canadian government has adopted this policy on the removal of Specified Risk Materials (SRM) from cattle slaughtered in Canada in order to prevent tissues that may contain BSE infectivity from entering the human food chain.

Every operator involved in the slaughter of cattle and/or the cutting/boning of bovine carcasses/quarters, shall implement the practices described in this annex, as required.

## 1.1 POLICY SUMMARY

Operators of establishments inspected under the *Meat Inspection Regulations, 1990* must

- take the appropriate measures to identify cattle aged 30 months or older and remove from these carcasses the skull including the brain, trigeminal ganglia and eyes, the tonsils, the spinal cord and the vertebral column including the dorsal root ganglia;
- remove the small intestine from cattle of all ages; and
- treat these materials referred to as Specified Risk Materials (SRM), as inedible meat products.

Operators are responsible for the development, implementation, and maintenance of control programs (including HACCP plans where appropriate) that address all components of this Specified Risk Material (SRM) removal policy.

## 1.2 EFFECTIVE DATE OF THE SRM POLICY

This policy will come into effect on **July 24, 2003**.

## 2.0 CATTLE AND CARCASS IDENTIFICATION

Operators slaughtering cattle of mixed age should make every effort to slaughter animals aged 30 months or older together.

Ear tags (e.g. the Canadian Cattle Identification Agency (CCIA) official tags) shall be attached, after their insertion into a plastic bag, to the fore shank of the carcass following hide removal. Alternative procedures that assure, with equal confidence, maintenance of the identity of the carcass and all its parts until their final disposition is known, may be approved by the veterinarian in charge.

## 2.1 DENTITION VERIFICATION, AGE DETERMINATION AND CARCASS IDENTIFICATION

The operator shall examine the incisor teeth of each carcass during post-mortem at or before the head inspector station. Plant personnel examining the teeth must be able to recognize permanent incisor teeth and be knowledgeable of this policy.

**For the purposes of this policy, cattle are considered to be aged 30 months or older when they have more than two permanent incisor teeth erupted (i.e. the first pair of permanent incisors and at least one tooth from the second pair of permanent incisors). See Appendix A for diagrams of bovine incisor teeth.**

When a carcass has been identified as being derived from an animal aged 30 months or older, it must be marked in a way that will permit easy identification of the head and the carcass sides (and quarters as needed) up to the point where all Specified Risk Materials (SRM) are removed.

Operators may be able to reduce or eliminate the need for certain requirements under this part if this does not affect the outcome of the policy. For example, an operator may decide to



treat all slaughtered cattle as being derived from animals aged 30 months or older. In such a case, Specified Risk Materials (SRM) would be removed from all carcasses regardless of their age. There would therefore be no need to mark the head and the carcass sides (unless the removal of the vertebral column is performed in another establishment).

A CFIA inspector will monitor the accuracy of the operator's examination of incisor teeth, aging and carcass identification during the inspection of the head. Their focus with respect to the age determination will be on carcasses that are judged by the operator to be under 30 months of age.

### **3.0 STUNNING, DRESSING AND SRM REMOVAL**

#### **3.1 STUNNING**

As per section 4.4.5 of this manual, the use of a penetrating percussion device which injects air into the cranial cavity is not permitted and the use of pithing rods is prohibited.

Any externalized brain tissue must be collected and treated as SRM (e.g. contaminated hide from the head). Special care must be taken not to cross contaminate meat products with brain tissue.

#### **3.2 HEAD SEPARATION AND REMOVAL OF SKULL, BRAIN, TRIGEMINAL GANGLIA, EYES AND TONSILS**

The skull including the brain, trigeminal ganglia, eyes and tonsils of cattle aged 30 months or older are SRM and must be disposed of as inedible products. Separating the head from the carcass risks spread of spinal cord to adjacent tissue. The removal of the head must be achieved without contamination of the carcass or other meat products with SRM ( i.e. spinal cord, brain) or other contaminants.

Separate knives must be provided for exclusive use in severing the spinal cords of cattle aged 30 months or older. These knives as well as steels must be identified by a color coding or other visual system. Standard washing and sanitizing procedures apply.

As soon as the inspection of the head is completed and the tongue and cheek meat have been harvested, the remainder of the head should be placed without delay in an inedible container of suitable dimensions to prevent subsequent contact between the SRM head and any meat products.

#### **3.3 TONGUE AND CHEEK MEAT**

Harvesting of tongue and cheek meat shall be carried out as soon as possible after the head has been removed. The tongue and cheek meat should be well washed after their removal, using a controlled wash which will not cause cross-contamination.

#### **3.4 REMOVAL OF THE DISTAL ILEUM**

In order to ensure complete removal of the distal ileum, the entire small intestine of all cattle regardless of their age must be removed and disposed of as inedible product. Best practice

is to dispatch the small intestinal contents with the small intestine.

### 3.5 CARCASS SPLITTING

The saw should separate the vertebral column in midline to facilitate removal of the spinal cord. Water used in an automatic rinse system for the saw must be controlled and ducted away from carcasses and edible offal. The water-exhaust effluent should be adequately trapped. The trap should be emptied, cleaned and renewed as and when necessary. All filtrate should be treated as SRM and should be emptied into an inedible container.

### 3.6 REMOVAL OF SPINAL CORD

The spinal cord of cattle aged 30 months or older is a SRM and must be removed in its entirety, on the kill floor before the final carcass wash, and disposed of as inedible product. Lifting the cord out of the vertebral canal can be achieved using a knife. Other specialized tools can be used, but chain link gloves are not suitable due to the increased risk of gross cross-contamination.

Separate knives or other tools must be provided for exclusive use in removing and handling spinal cords of cattle aged 30 months or older. These knives/tools, as well as steels must be identified by a color coding or other visual system. Standard washing and sanitizing procedures apply.

**Note:** The spinal cord of cattle less than 30 months of age is not designated as a SRM but, nevertheless, must still be completely removed from all split carcasses on the kill floor before the final carcass wash. In the case of carcasses that are split after chilling (i.e. hide-on veal carcasses), the spinal cord must be removed during boning/cutting operations. This is required to prevent incorporation of spinal cord tissue into any meat products, ensuring compliance with established meat product standards and simplifying verification measures.

### 3.7 VERIFICATION OF COMPLETE REMOVAL OF SPINAL CORD

Remnants of spinal cord, may be present at the final inspection. This is potentially the most important control point. The operator must make a thorough check of every carcass to ensure that no remnants of spinal cord are present before the carcass is marked with the meat inspection legend. This check must be performed for each carcass side. When any spinal cord remnant is discovered, the carcass must be retained for immediate rework by the operator.

### 3.8 REMOVAL OF THE DORSAL ROOT GANGLIA

In order to ensure complete removal of the dorsal root ganglia, the vertebral column of cattle aged 30 months or older, excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum, must be removed and disposed of as inedible product. This will most likely be done in the cut-up/boning room using normal boning procedures. In the case of establishments that do not have a boning facility, the removal of the vertebral column can be performed in another federally inspected establishment. Slaughter establishments that do not remove the SRM vertebral column on site will have to implement an identification system and shipping controls satisfactory to the



veterinarian in charge. The controls should include notification of the inspector in charge of the receiving establishment where the removal of the vertebral column will take place regarding the number of carcasses or quarters to be expected. The receiving establishment must have a verifiable control system in place which will demonstrate to the satisfaction of the inspector in charge that all parts of the vertebral column are removed and appropriately disposed.

Note: The vertebral column of cattle aged 30 months or older, cannot be used as raw material in the preparation of mechanically separated meat or finely textured meat.

### **3.9 VERIFICATION BY THE OPERATOR OF SRM REMOVAL AND REWORK**

The operator must verify the complete removal of all SRM. Any carcass or part that is found to be harbouring fragments of SRM (e.g. spinal cord) must be retained by the operator for rework and subsequent presentation for further examination by the operator. The operator should have a system which allows retention and rework of carcasses harbouring residual SRM to occur successfully and without gross SRM cross contamination to meat products. The operator must be able to demonstrate control of the system at all times.

## **4.0 SRM HANDLING AND DISPOSITION**

This section describes effective separation of SRM from the carcass, provisions for storage of SRM and hygienic standards associated with floor waste and inedible containers. Because of structural differences between establishments, procedures for separating and isolating the various SRM may vary. Generally, separation of SRM should occur as soon as possible and care should be taken to avoid gross contamination of meat products and the establishment environment by SRM.

### **4.1 HANDLING OF SRM WITHIN THE ESTABLISHMENT**

SRM should be separated from carcasses at the earliest opportunity during the dressing process. SRM should be placed in inedible containers without delay and regularly moved to the inedible products area. This must include all SRM separated from the carcass, SRM from the floor and gross SRM debris. Basic principles of hygiene must be observed at all times.

### **4.2 FLOOR WASTE**

Areas where SRM are removed or handled should be regularly attended to by cleaners. Systems for containing gross debris and operational cleaning of these areas is important. SRM shoveled from the floor and any SRM debris from channels and drain covers/traps should be deposited into an inedible container. Use of squeegees is recommended. Drain covers and traps should be lifted and all matter collected from these sources shall be deposited into an inedible container, at least at the end of each working day.

### **4.3 SRM CONTAINERS**

It is important that all SRM and debris are contained within inedible containers. Containers that leak shall not be used until they are repaired.

#### 4.4 CLEANING OF SRM CONTAINERS

All equipment and containers used in the handling of SRM must be routinely cleaned and sanitized. Inedible containers must at all times be acceptably clean. If inedible containers are being returned by a rendering company in an unclean state they shall not be used until they are cleaned and sanitized. Cleaning of inedible containers should not occur where there are meat products in the vicinity. The cleaning and sanitizing of inedible containers should be an integral part of the cleaning schedule of the premises, and verified during the pre-operational inspection.

#### 5.0 SRM CONTROLS

The operator is responsible for the development, implementation, and maintenance of documented control programs that address all the components of this SRM removal policy including age determination and carcass identification. The control programs must ensure compliance with the relevant provisions of the Meat Hygiene Manual of Procedures (MOP), the *Meat Inspection Regulations, 1990* and the *Health of Animals Regulations* with respect to the control and disposition of bovine SRM and inedible material, including dead stock (dead on arrival) material. Operators who have implemented a HACCP system are expected to modify it accordingly.

All appropriate staff including supervisors and managers should have broad and current knowledge of the potential risk of BSE to the human population as well as the risk to the national cattle herd. The operator and all staff should have demonstrable knowledge of the establishment's SRM control programs and be able to demonstrate with accurate records that the SRM controls they have put in place, have been implemented in practice, resulting in full compliance with the regulations and policy requirements.

CFIA inspection personnel must be able to demonstrate their thorough familiarity with the SRM control programs established by the operator and to verify full compliance with relevant regulations and this policy through the completion of relevant MCAP tasks and other inspection records as required.

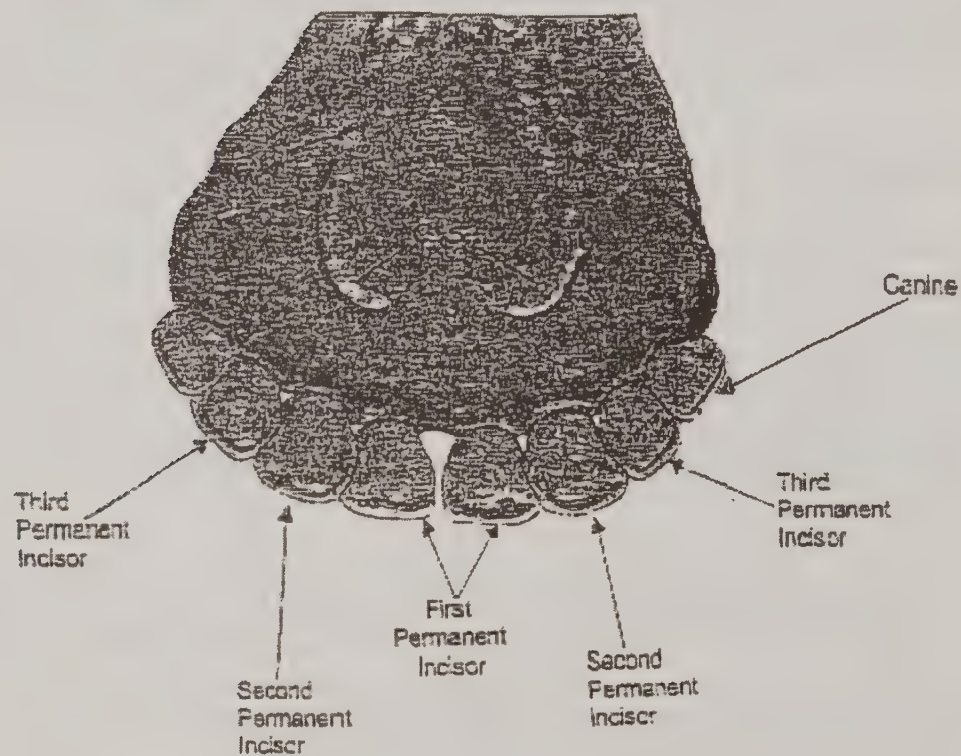
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## APPENDIX A

### CATTLE DENTITION

Figure 1

Permanent Teeth Lingual Aspect  
Incisor and Canine Teeth of Ox 5 years of age



Extract: Sisson and Grossman's  
The Anatomy of the Domestic Animals  
Volume I

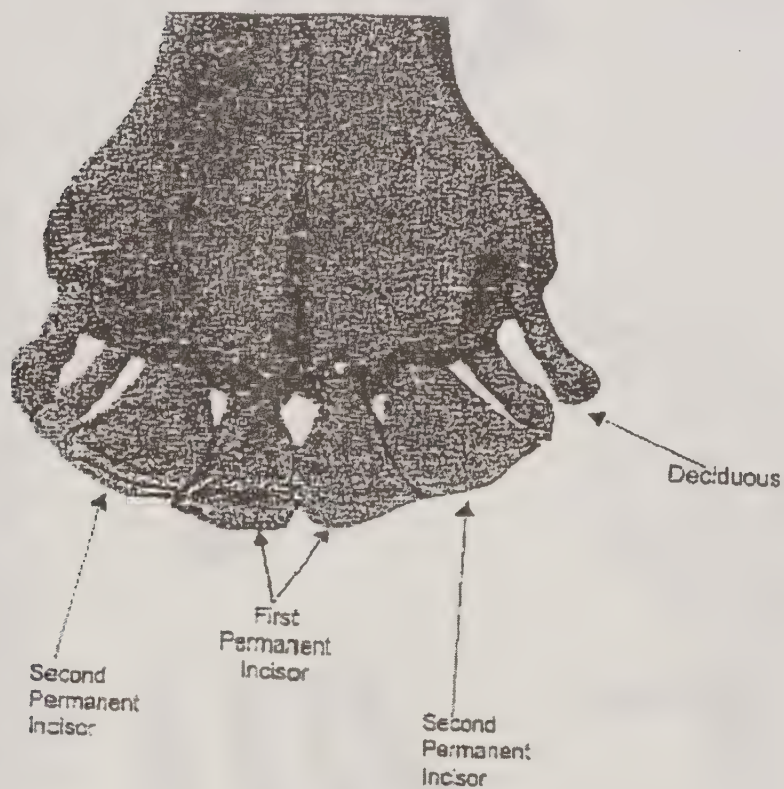
## APPENDIX A

### CATTLE DENTITION



Figure II

Permanent Teeth Lingual Aspect  
Incisor and Canine Teeth of Ox 2 ½ years of age



Extract: Sisson and Grossman's  
The Anatomy of the Domestic Animals  
Volume I

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## APPENDIX A

### CATTLE DENTITION

**Figure III**

**Permanent Teeth Lingual Aspect  
Incisor and Canine Teeth of Ox**

**Permanent  
aged**



**Permanent**



**Deciduous**



**Extract: Sisson and Grossman's  
The Anatomy of the Domestic Animals  
Volume I**

**APPENDIX B  
Cattle Vertebral Column  
Figure I**



## RUMINANT

FIGURE 35-1. Bovine dura mater enclosed spinal cord; dorsal view (spinal cord segment indicated by broken lines).

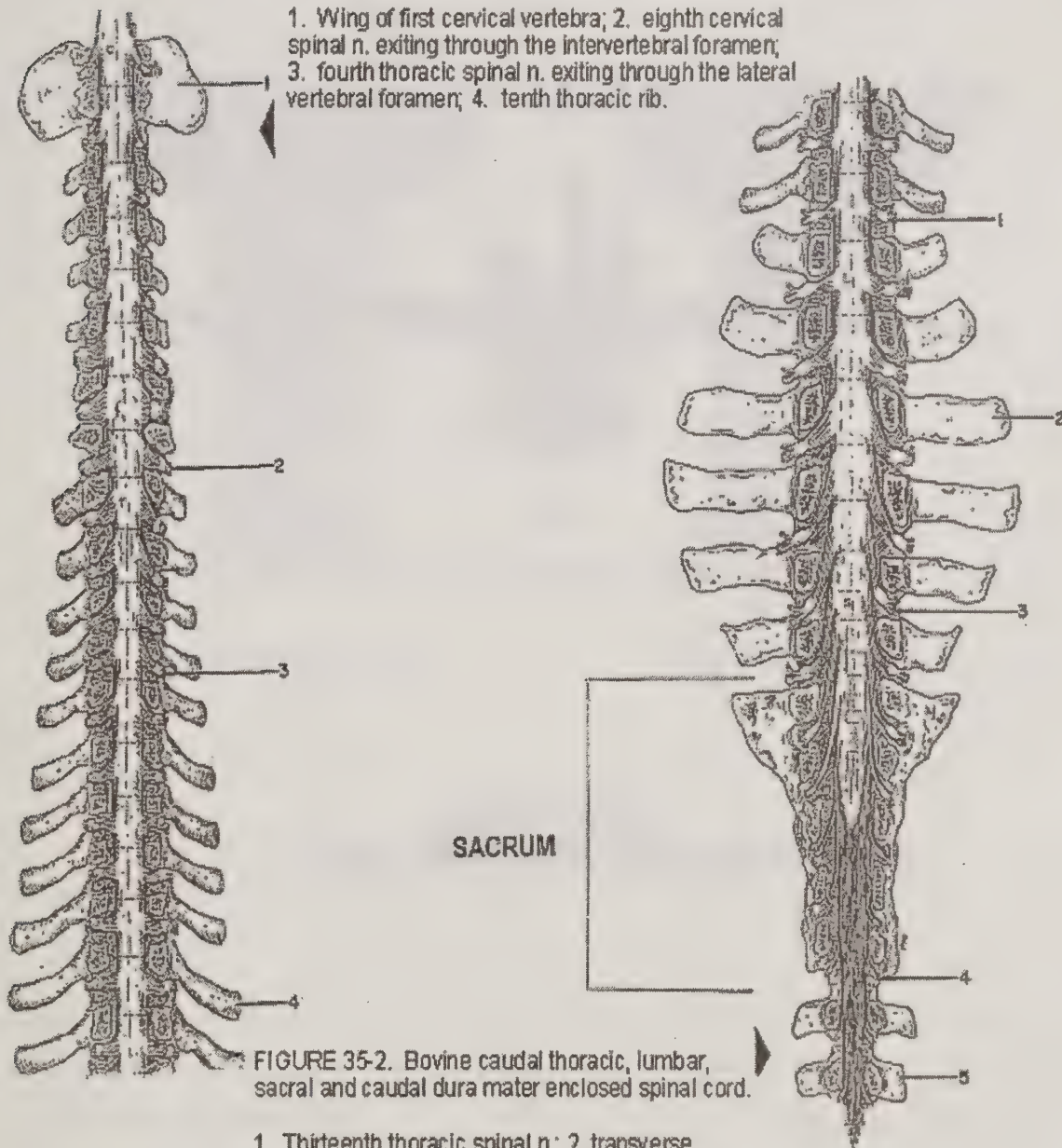
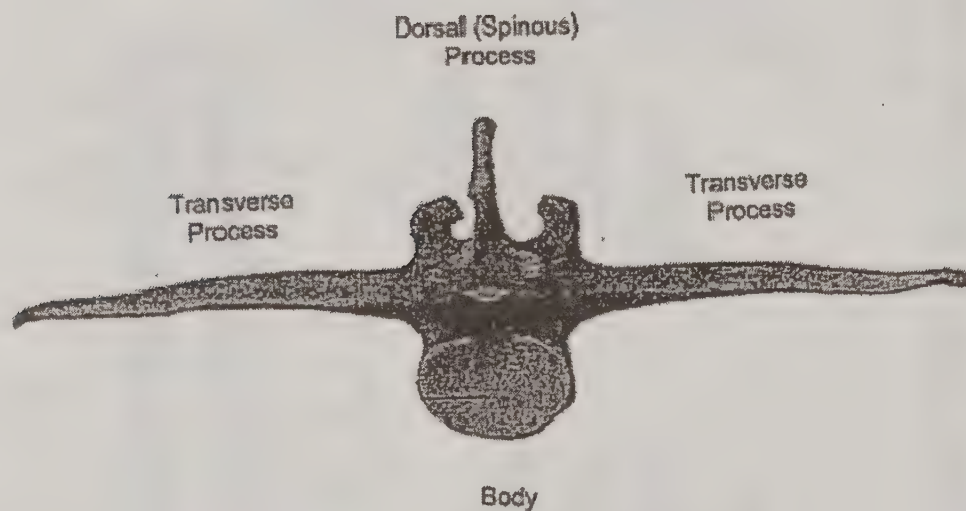


FIGURE 35-2. Bovine caudal thoracic, lumbar, sacral and caudal dura mater enclosed spinal cord.

1. Thirteenth thoracic spinal n.; 2, transverse process of third lumbar vertebra; 3, sixth lumbar spinal n.; 4, fifth sacral spinal n.; 5, second caudal (coccygeal) vertebra.

Extracted From  
**Sisson and Grossman's**  
**The Anatomy of the Domestic Animals - Volume 1**

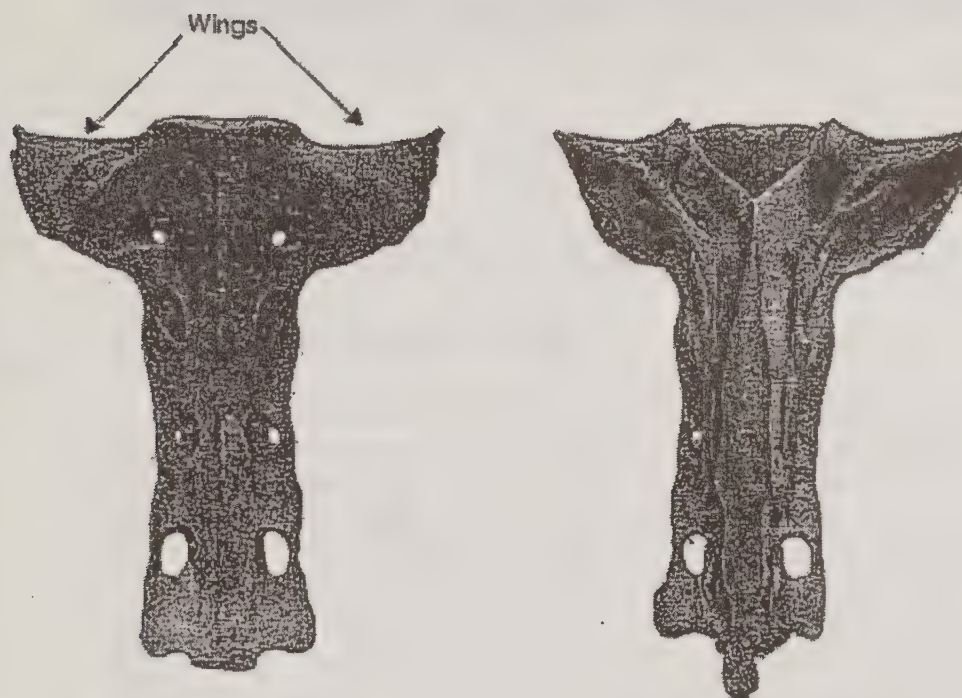
APPENDIX B  
Cattle Vertebral Column  
Figure II



Fourth lumbar vertebra of ox; caudal view.

Extracted From  
*Sisson and Grossman's*  
*The Anatomy of the Domestic Animals - Volume 1*

APPENDIX B  
Cattle Vertebral Column  
Figure III



Sacrum of ox; ventral view.

Sacrum of ox; dorsal view

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*The Anatomy of the Domestic Animals - Volume 1*

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Canadian Food  
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Agence canadienne  
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## Canadian Food Inspection Agency Industry Fact Sheet

# SPECIFIED RISK MATERIALS

### Specified Risk Materials (SRM)

In Canada, the following tissues are defined in regulation as SRM: skull, brain, trigeminal ganglia (clusters of nerve cells connect to the brain and closely apposed to the exterior of the skull), eyes, tonsils, spinal cord, and dorsal root ganglia (clusters of nerve cells connected to the spinal cord and closely apposed to the vertebral column) of cattle aged 30 months or older, and the distal ileum (part of the small intestine) of cattle of all ages. Specified risk materials, with the exception of the skull, are tissues that, in BSE-infected cattle, have been shown to contain the infective agent and transmit the disease. The skull has been designated because of the high probability of it becoming contaminated at the time of stunning and during manipulation of the other tissues if their separate removal was permitted. The SRM must be removed at slaughter or, in the case of the dorsal root ganglia, during the cutting/boning process, and disposed of along with other inedible material from the establishment.

In order to ensure complete removal of the dorsal root ganglia, operators are required to remove the vertebral column from cattle aged 30 months and older. For the purposes of this policy, the definition of the vertebral column excludes the vertebrae of the tail, the transverse processes of the lumbar and thoracic vertebrae, and the wings of the sacrum. The CFIA and Health Canada will entertain proposals from industry on possible changes to this definition that would increase economic return while still providing the necessary assurance of complete removal of the dorsal root ganglia. In any case, the vertebral column of cattle over 30 months of age cannot be used as raw material in the preparation of mechanically separated meat or finely textured meat.

Similarly, in order to ensure removal of the distal ileum in a manner that can be verified by inspection staff, operators are required to remove the entire small intestine from cattle of all ages. This requirement may be modified when procedures are identified that would enable removal of the distal ileum in a manner that is visually verifiable by inspection staff.

### Implementation



In accordance with Meat Hygiene Directive 2003-18, the effective date for implementation of the SRM removal policy in federally registered establishments is July 24, 2003.

As of August 23, 2003, the requirement to remove the SRM will apply by regulation to all businesses and individuals who slaughter cattle in Canada and, in the case of the vertebral column, to all businesses and individuals who cut up or debone carcasses or quarters of cattle over 30 months of age to produce beef or beef products for human consumption.

Directive 2003-18 describes requirements for the removal, identification, control and disposition of SRM. While the Directive was developed for application in federally registered establishments it can also serve as a guide or reference document for other jurisdictions.

### **Background**

While BSE is a cattle disease, the human disease called variant Creutzfeldt-Jacob Disease (vCJD) has been associated with the consumption of products derived from BSE-infected cattle. Cattle tissues identified as SRM are not generally consumed as food. However, during processing, SRM could be unintentionally included in meat products destined for human consumption.

The SRM policy is being introduced to prevent tissues that may contain BSE infectivity from entering the human food chain and thereby further enhance public health protection. The detection of the one case of BSE has not compromised the safety of Canada's food supply. Although only one animal has been found to date to be infected with BSE, taking action to remove SRM from cattle at slaughter will further enhance the safety of the food supply in Canada. Canada's food supply is also protected from BSE by the CFIA's feed ban, import restrictions and routine animal surveillance. The development of this new policy on SRM removal reflects the government's commitment to strengthening Canada's BSE measures and to protecting the health of Canadians.

### **Where Can I Find More Information?**

#### *Policy Information*


- Policy on Specified Risk Materials of Bovine Origin in the Food Supply <http://www.hc-sc.gc.ca/english/diseases/bse/index.html>
- Removal of Specified Risk Materials from Cattle Slaughtered in Establishments Inspected Under the *Meat Inspection Regulations* <http://www.inspection.gc.ca/english/animal/meavia/mmopmmhv/direct/2003/direct18e.shtml>

#### *Background Information*

- Canadian Food Inspection Agency's BSE Investigation  
<http://www.inspection.gc.ca/english/animas/heasan/disemala/bseesb/bseesbindexe.shtml>
- Variant Creutzfeldt-Jacob Disease  
<http://www.hc-sc.gc.ca/english/diseases/cjd/bg4.html>

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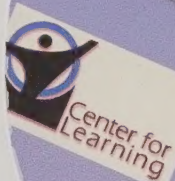






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D:\setup (substitute  
CD drive letter if  
different). Click OK.



To Run Program  
Place CD in the  
player. Click on Start  
highlight Programs  
highlight Training  
Click on BSE.

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Place the CD in the CD player.  
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